

erfsfarch | regiii atory management

Date: Saturday, June 22, 2019 5:06:25 PM

Print

01. General Study Information

All questions marked with a red asterisk (*) require a response. Questions without a red asterisk may or may not require a response, depending on those questions' applicability to this study.

1.1* Study Title:

Assessing the prevalence of food insecurity and barriers to food access in the Middle Eastern refugee population of Southeast Michigan

1.1.1 Full Study Title:

Assessing the prevalence of food insecurity and barriers to food access in the Middle Eastern refugee population of Southeast Michigan

1.1.2 If there are other U-M studies related to this project, enter the eResearch ID number (HUM#) or IRBMED Legacy study number. Examples of related projects include, but are not limited to:

- Projects funded under the same grant
- IRBMED Legacy study being migrated into eResearch
- Previously approved Umbrella applications (such as Center Grants or approvals for release of funding)
- Previously approved projects for which this is a follow up study

1.2* Principal Investigator:

Brent Williams

Note: If the user is not in the system, you may Create A New User Account.

1.3 Study Team Members:

| Study Team Member | Study Team Role | Appointment Dept | Appointment Selection Complete? | Student | Friend Account | COI Review Required | Edit Rights | Accepted Role? | PEERRS Human Subjects? |
|-------------------------|-----------------------|---------------------------------|---------------------------------------|---------|-------------------|---------------------------|----------------|----------------|------------------------------|
| Brent Williams | PI | Int Med- General Medicine | Yes | no | No | no | yes | N/A | yes |
| Marwa Ayyash | Co- Investigator | | N/A | yes | No | no | yes | Yes | yes |
| Christina Ceci | Co- Investigator | | N/A | yes | No | no | yes | Yes | yes |
| Anne Kalinowsk | Co- i Investigator | | N/A | yes | No | no | yes | Yes | yes |
| Deborah Trimble | Co- Investigator | | N/A | yes | No | no | yes | Yes | yes |
| Nathan Vengalil | Co- Investigator | | N/A | yes | No | no | yes | Yes | yes |

1.8* Project Summary:

During fiscal year 2016, the United States admitted 84,995 refugees across its borders, a majority of these refugees hailed from Middle Eastern nations (Green, 2017). Of these newcomers, 5,039 refugees resettled in Michigan, the majority being from Syria or Iraq (Tanner, 2017). With the present influx of refugees into the United States, it has become necessary to explore the barriers facing these newcomers. Previous studies have demonstrated that refugee populations are at increased risk for food insecurity, which is defined as having a limited ability or uncertainty in accessing adequate, nutritious, or acceptable food (Vahabi and Damba, 2013). Refugees are more likely to face food insecurity for a variety of reasons which include: low household income (Hadley et al., 2010), shorter length of resettlement (Hadley et al., 2006), and language barriers (Vahabi and Damba, 2013). Acculturation, the outcome and

process through which immigrants acquire and react to food-related habits of the dominant society, has also been linked to food insecurity (Hadley, et al., 2006). Importantly, food insecurity has been correlated with negative health outcomes such as cardiovascular disease and mental health conditions (McIntyre et al., 2009).

In the present study, we are interested in refugees that have resettled in Southeast Michigan, as Michigan accepts the second highest amount of refugees in the U.S. (Tanner, 2017). There are many programs located in Michigan that function to aid refugees. One such program is the Arab Community Center for Economic and Social Services (ACCESS) whose goal is to enable and empower individuals, families, and communities to lead informed, productive, and culturally sensitive lives. Our aim is to improve the services and delivery of resources that are available through ACCESS by assessing the prevalence of food insecurity and factors that influence food insecurity among recent immigrants to Southeast Michigan. We hypothesize that among refugees there will be higher levels of food insecurity, that lower food literacy and shorter length of stay in the United States will be correlated with higher levels of food insecurity, and that greater levels of acculturation will be correlated with lower food insecurity.

To assess levels of food insecurity, a short survey will be given in a sequential manner to 100 members of the community who visit the health clinic at ACCESS. All survey data will be completely anonymized at the point of data collection. Surveys will only be given to participants who are 18 years of age or older. We will obtain demographic information regarding country of origin, refugee status, length of stay in the US, proficiency in English, income level, education level, and number of persons in the household. Validated questions from the Six-Item U.S. Household Food Security Survey Modules will be used to assess individual/household food insecurity. Additional questions will ask about personal barriers to food access based on acculturation and food label literacy. To ensure that participation in the survey will be accessible to all members of the community, the survey will be translated into both English and Arabic. Data analysis of survey responses will then be performed at the University of Michigan Medical School.

Based on survey results, participants will be split into two categories: recent refugees from Middle Eastern countries of origin (recent is defined as arriving within the past 10 years) and non-refugees or refugees that have lived in the US for greater than 10 years. In each group, levels of food insecurity will be assessed. A difference in food insecurity level will be considered significant if there is a p-value-0.05. For each group, a qualitative analysis will then be performed to assess the factors that are contributing to food insecurity. Thus, based on the data we collect, we hope to identify areas of need related to food insecurity in the refugee population that visits ACCESS and use this information to help improve the services offered by ACCESS. Additionally, collected survey data could also be used for further research analysis in the future.

| 1.9* Select the appropriate IRB: |
|---|
| IRBMED |
| |
| 1.11* Estimated Duration of Study: |
| Two years (24 months) |
| 01-1. Application Type |
| 1-1.1* Select the appropriate application type. |
| Exempt Human Subject Research |
| 01-2. Standard Study Information |
| 1-2.1* Who initiated this study? |
| Student investigator or faculty member on behalf of a student |
| 1-2.2* Are you or any students working on this project being paid from a federally funded training grant? |
| ◯ Yes ● No |
| 1-2.3 This study is currently associated with the following department. To associate this |

1-2.3 This study is currently associated with the following department. To associate this research with a different department, click Select. If the department has defaulted to "student", click select to specify the department through which this application is being submitted.

| Medical School |
|---|
| 1-2.5* Is the study related to cancer, cancer risk, or cancer care delivery? |
| ◯ Yes ● No |
| 1-2.7* Has the scientific merit of this study already been peer reviewed (i.e., reviewed by one or more recognized authorities on the subject)? |
| ○ Yes ● No |
| 1-2.8* Is this a clinical trial? |
| ◯ Yes ● No |
| 1-2.9° Would the integrity of this research study be compromised if the subject were able to view results of their research tests or medications in the Patient Portal of MyUofMHealth.org? Research results displayed to the subject in MyUofMHealth.org will include: lab results, radiology examinations and outpatient medication lists. Contracts and protocols should be assessed by the Principal Investigator for specific language regarding blinding of subjects and their research results. |
| (NOTE: Additional actions are required in order to limit the subject's view into their electronic medical record. Contact the IRB for additional information or see additional guidance for blinded studies at https://az.research.umich.edu/medschool/guidance/guidance-blinded-studies) |
| ○ Yes ● No |
| 01-7. Student Research Information |
| 1-7.1* This application is being submitted by a: |
| Select all that apply: |
| Faculty member on behalf of a student for a course, internship, dissertation/thesis. |
| 1-7.2 Indicate course number here: |
| Study Team Detail |
| 1.4 Team Member: |
| Brent Williams |
| Preferred email: bwilliam@umich.edu Business phone 734-615-3636 Business address: Int Med - General Medicine NCRC 2800 Plymouth Rd Bldg 16/447E 48109-2800 |
| 1.5 Function with respect to project: |
| PI |
| 1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process: |
| Yes |

Credentials: Required for PI, Co-Is and Faculty Advisors

| pload or update your CV, resume, or biographical sketch. | |
|---|--|
| Name | Version |
| ♥ Williams Brent CV 6-11-18 (1).docx | 0.05 |
| Conflict of Interest Detail: Required for all roles | except Administrative Staff |
| urrent Disclosure Status in M-Inform: This study team mem lationship(s) in M-Inform. | ber has disclosed outside interest(s) or |
| 1 Do you have an outside interest or a relationship* with a non: : | -UM entity, where the non-UM entity |
| Sponsoring this project; Supplying products purchased for this project; Providing a product used in this project (e.g., an app, device evaluation); Holding an option/license to intellectual property used in the drug, software, survey, evaluation) that you developed; or Receiving a subcontract for work on this project? | |
| Examples of relevant interests or relationships with a non-UM encome from, consulting with, serving as an officer/director/advisonancial/leadership interest or relationship with that entity. | |
| lo | |
| D2 If "Yes" to the question above, provide the name of the o description of the interest/relationship(s): | utside entity or entities and a brief |
| .4 Team Member: | |
| Jarwa Ayyash | |
| Preferred email: ayyashm@umich.edu Business phone Business address: LSA Chemistry Rm 1416 Chemistry Blo | dg 48109-1055 |
| .5 Function with respect to project: | |
| Co-Investigator | |

| | ow this person to EDIT th ted during the review pro | ne application, including any supporting documents/stipulations ocess: | |
|--------------|--|--|--|
| Yes | | | |
| include | | orrespondences regarding this application: (Note: This will ndence, decision outcomes, renewal notices, and adverse event | |
| Yes | | | |
| Crede | ntials: Required for | PI, Co-Is and Faculty Advisors | |
| Upload | or update your CV, resu | me, or biographical sketch. | |
| | Name | Version | |
| Ð | Marwa-CV | 0.01 | |
| Conf | lict of Interest Detail | : Required for all roles except Administrative Staff | |
| Curren | t Disclosure Status in M-I | Inform: This study team member has not yet disclosed in M-Inform. | |
| D1 Do is: | you have an outside intere | est or a relationship* with a non-UM entity, where the non-UM entity | |
| • (| evaluation); | this project (e.g., an app, device, compound, drug, software, survey, | |
| (| | o intellectual property used in this project (e.g., a device, compound, luation) that you developed; or r work on this project? | |
| income | | relationships with a non-UM entity include owning stock in, receiving ing as an officer/director/advisor to, or having some other related tionship with that entity. | |
| No | | | |
| | | | |
| | Yes" to the question aboution of the interest/relation | ve, provide the name of the outside entity or entities and a brief onship(s): | |
| | | | |
| tudy 1 | Team Detail | | |
| 1.4 Tea | am Member: | | |
| Christin | a Ceci | | |

Preferred email: cceci@umich.edu

| Business phone Business address: | 48109 | | |
|--|--|--|--|
| 1.5 Function with respec | t to project: | | |
| Co-Investigator | | | |
| 1.6 Allow this person to l requested during the revi | | nny supporting documents/stipulations | |
| Yes | | | |
| | | g this application: (Note: This will ss, renewal notices, and adverse event | |
| Yes | | | |
| Credentials: Require | d for PI, Co-Is and Faculty | Advisors | |
| Upload or update your C\ | , resume, or biographical sketc | h. | |
| Name | | Version | |
| Christina Ceci CV | | 0.01 | |
| Conflict of Interest | Detail: Required for all ro | es except Administrative Staff | |
| Conflict of Interest | Detail: Required for all ro | es except Administrative Staff | |
| | | les except Administrative Staff nember has not yet disclosed in M-Inform. | |
| Current Disclosure Status D1 Do you have an outsic | in M-Inform: This study team r | | |
| Current Disclosure Status D1 Do you have an outsid is: Sponsoring this proj Supplying products Providing a product | e interest or a relationship* with a | nember has not yet disclosed in M-Inform. | |
| D1 Do you have an outsidis: Sponsoring this projes Supplying products Providing a product evaluation); Holding an option/lic drug, software, surv | e interest or a relationship* with a sect; surchased for this project; used in this project (e.g., an app, or sect). | nember has not yet disclosed in M-Inform. non-UM entity, where the non-UM entity device, compound, drug, software, survey, in this project (e.g., a device, compound, | |
| Current Disclosure Status D1 Do you have an outsid is: Sponsoring this proj Supplying products Providing a product evaluation); Holding an option/lic drug, software, surv. Receiving a subcont "Examples of relevant inter | e interest or a relationship* with a ect; purchased for this project; used in this project (e.g., an app, cense to intellectual property used ey, evaluation) that you developed ract for work on this project? | nember has not yet disclosed in M-Inform. non-UM entity, where the non-UM entity device, compound, drug, software, survey, in this project (e.g., a device, compound, | |
| Current Disclosure Status D1 Do you have an outsid is: Sponsoring this proj Supplying products Providing a product evaluation); Holding an option/lic drug, software, surv. Receiving a subcont "Examples of relevant inter | e in M-Inform: This study team re e interest or a relationship* with a ect; purchased for this project; used in this project (e.g., an app, or ense to intellectual property used exp, evaluation) that you developed ract for work on this project? ests or relationships with a non-UI h, serving as an officer/director/ac | nember has not yet disclosed in M-Inform. non-UM entity, where the non-UM entity device, compound, drug, software, survey, in this project (e.g., a device, compound, ; or M entity include owning stock in, receiving | |
| D1 Do you have an outsides: Sponsoring this project Supplying products Providing a product evaluation); Holding an option/lic drug, software, survenees a subcontext of the property of the product of the provided program of the provided program of the provided pro | e in M-Inform: This study team re e interest or a relationship* with a ect; purchased for this project; used in this project (e.g., an app, or ense to intellectual property used exp, evaluation) that you developed ract for work on this project? ests or relationships with a non-UI h, serving as an officer/director/ac | nember has not yet disclosed in M-Inform. non-UM entity, where the non-UM entity device, compound, drug, software, survey, in this project (e.g., a device, compound, ; or M entity include owning stock in, receiving | |
| D1 Do you have an outsides: Sponsoring this project Supplying products Providing a product evaluation); Holding an option/lic drug, software, survenees a subcontext of the property of the product of the provided program of the provided program of the provided pro | e in M-Inform: This study team re e interest or a relationship* with a ect; purchased for this project; used in this project (e.g., an app, or ense to intellectual property used exp, evaluation) that you developed ract for work on this project? ests or relationships with a non-UI h, serving as an officer/director/ac | nember has not yet disclosed in M-Inform. non-UM entity, where the non-UM entity device, compound, drug, software, survey, in this project (e.g., a device, compound, ; or M entity include owning stock in, receiving | |

Study Team Detail

1.4 Team Member:

Anne Kalinowski

Preferred email: annekal@umich.edu

Business phone

Business address: 48109

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

| | Name | Version |
|----------|------------------------|---------|
| 5 | CV for Anne Kalinowski | 0.02 |

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: This study team member has not yet disclosed in M-Inform.

D1 Do you have an outside interest or a relationship* with a non-UM entity, where the non-UM entity is:

- Sponsoring this project;
- · Supplying products purchased for this project;
- Providing a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation);
- Holding an option/license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation) that you developed; or
- Receiving a subcontract for work on this project?

*Examples of relevant interests or relationships with a non-UM entity include owning stock in, receiving income from, consulting with, serving as an officer/director/advisor to, or having some other related financial/leadership interest or relationship with that entity.

No

| D2 If "Yes" to the question above, provide the name of the outside entity description of the interest/relationship(s): | or entities and a brief |
|--|-------------------------|
| | |

Study Team Detail

1.4 Team Member:

Deborah Trimble

Preferred email: detrimbl@umich.edu

Business phone

Business address: 48109

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

| | Name | Version |
|----------|------------|---------|
| 9 | Trimble CV | 0.01 |

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: This study team member has not yet disclosed in M-Inform.

D1 Do you have an outside interest or a relationship* with a non-UM entity, where the non-UM entity is:

- Sponsoring this project;
- Supplying products purchased for this project;
- Providing a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation);

| C | Holding an option/license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation) that you developed; or Receiving a subcontract for work on this project? |
|---------|---|
| *Examp | ples of relevant interests or relationships with a non-UM entity include owning stock in, receiving from, consulting with, serving as an officer/director/advisor to, or having some other related al/leadership interest or relationship with that entity. |
| No | |
| | |
| | |
| | |
| | 'Yes" to the question above, provide the name of the outside entity or entities and a brief ption of the interest/relationship(s): |
| tudy 1 | Team Detail |
| 1 4 Te: | am Member: |
| | vengalil |
| | red email: nvengali@umich.edu |
| | ess phone |
| Busine | ess address: 48109 |
| 1.5 Fu | nction with respect to project: |
| Co-Inve | estigator |
| | low this person to EDIT the application, including any supporting documents/stipulations sted during the review process: |
| Yes | |
| include | clude this person on all correspondences regarding this application: (Note: This will e all committee correspondence, decision outcomes, renewal notices, and adverse event ssions.) |
| Yes | |
| | entials: Required for PI, Co-Is and Faculty Advisors |
| Crede | |
| | d or update your CV, resume, or biographical sketch. |
| | d or update your CV, resume, or biographical sketch. Name Version |
| | |

Current Disclosure Status in M-Inform: This study team member has not yet disclosed in M-Inform.

D1 Do you have an outside interest or a relationship* with a non-UM entity, where the non-UM entity

- Sponsoring this project;
- Supplying products purchased for this project;
- Providing a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation);
- Holding an option/license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation) that you developed; or
 Receiving a subcontract for work on this project?

*Examples of relevant interests or relationships with a non-UM entity include owning stock in, receiving income from, consulting with, serving as an officer/director/advisor to, or having some other related financial/leadership interest or relationship with that entity.

| No | |
|--|--|
| | |
| | |
| | |
| D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s): | |

02. Sponsor/Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.

* Note: At least one of the following sections must be answered. Multiple forms of funding or support must be added one at a time.

| 2.1 Please select all Proposal Approval Forms (PAFs), Awards (AWDs), and/or Unfunded Agreements (UFAs) associated with this study. |
|---|
| ☐ Click here to indicate that a PAF(s) has not been initiated. |
| Related PAFs: ID Title PI Direct Sponsor Prime Sponsor State Has SUBKs? Related Awards There are no items to display |
| Related AWDs: Award ID Title PI Direct Sponsor Prime Sponsor State Has SUBKs? Project Period Awarded PAFs There are no items to display |
| Related UFAs: UFA ID Title PI State Category Start Date End Date There are no items to display |
| 2.2 Internal UM Sponsor(s)/Support: [Including department or PI discretionary funding] |
| Type Department Sponsor Support Type There are no items to display |
| 2.3 Check here if the proposed study does not require external or internal sponsorship or support: |
| |
| 2.4* Is there any other financial or non-financial sponsorship or support not covered in the sections above? |
| ● Yes ○ No |
| 2.4.1* Please describe the other sponsorship/support: |
| This is a joint medical student-ACCESS project without specific funding, completed as part of Global Health and Disparities Path of Excellence. |

03. UM Study Functions

3.1^{\star} Indicate all functions that will be performed at University of Michigan locations.

Select all that apply:

Primary or secondary analysis (data/specimen)

Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify.

5-3. Research Design - Exempt Project

Completion of this section is required based on the response provided to question 1-1.1

5-3.1 Upload scientific protocol if one is available.

Name Version

There are no items to display

5-3.2* Describe the objective and specific aims of the project. If included in the attached protocol, please indicate the section.

During fiscal year 2016, the United States admitted 84,995 refugees across its borders, a majority of these refugees hailed from Middle Eastern nations (Green, 2017). Of these newcomers, 5,039 refugees resettled in Michigan, the majority being from Syria or Iraq (Tanner, 2017). With the present influx of refugees into the United States, it has become necessary to explore the barriers facing these newcomers. Previous studies have demonstrated that refugee populations are at increased risk for food insecurity, which is defined as having a limited ability or uncertainty in accessing adequate, nutritious, or acceptable food (Vahabi M and Damba V, 2013). Refugees are more likely to face food insecurity for a variety of reasons which include: low household income (Hadley et al., 2010), shorter length of resettlement (Hadley et al., 2006), and language barriers (Vahabi M and Damba V, 2013). Acculturation, the outcome and process through which immigrants acquire and react to food-related habits of the dominant society, has also been linked to food insecurity (Hadley C, et al., 2006). Importantly, food insecurity has been correlated with negative health outcomes such as cardiovascular disease and mental health conditions (McIntyre et al., 2009).

In the present study, we are interested in increasing the knowledge about levels of food insecurity and barriers to food access in refugees that have recently resettled in Southeast Michigan, as Michigan accepts the second highest amount of refugees in the U.S. (Tanner, 2017). There are many programs located in Michigan that function to aid refugees. One such program is the Arab Community Center for Economic and Social Services (ACCESS) whose goal is to enable and empower individuals, families, and communities to lead informed, productive, and culturally sensitive lives. Our aim is to assess the prevalence of food insecurity and factors that influence food insecurity among recent immigrants to Southeast Michigan such that ACCESS can use this data in order to better tailor interventions to the needs of refugee populations. We hypothesize that among refugees there will be higher levels of food insecurity, that lower food literacy and shorter length of stay in the United States will be correlated with higher levels of food insecurity, and that greater levels of acculturation will be correlated with lower food insecurity.

References

- 1. Green, M. "MAP: How Many Immigrants Did the U.S. Let In Last Year?" 4 Feb 2017. Accessed: 18 Aug 2017. URL: https://ww2.kqed.org/lowdown/2017/02/04/who-are-the-refugees-living-in-america-today/
- 2. Tanner, K. "Raw Data: Refugees in Michigan, by the numbers" 31 Jan 2017. Accessed: 18 Aug 2017. URL: http://www.freep.com/story/opinion/contributors/raw-data/2017/01/31/raw-data-refugees-michigan-numbers/97238722/.
- 3. Vahabi M and Damba V. Perceived barriers in accessing food among recent Latin American immigrants in Toronto. International Journal for Equity in Health. 2013; 12:1-11.
- Hadley C, Patil C, and Nahayo D. Difficulty in the food environment and the experience of food insecurity among refugees resettled in the United States. Ecology of Food and Nutrition.2010;49(5):390-407
- 5. Hadley C, Zodhiates A, and Sellen DW. Acculturation, economics, and food insecurity among refugees resettled in the United States: a case study of West African refugees. Public Health Nutrition. 2006; 10(4):405-412.
- 6. McIntyre L, Rondeau K: Food insecurity. In Social determinants of health: Canadian perspectives. Edited by Raphael D. Toronto, Ontario, Canada: Canadian Scholars' Press Inc; 2009:188–204.
- 7. Arab Community Center for Economic and Social Services. Retrieved from:
- https://www.accesscommunity.org/.

5-3.3* Describe the scientific design of the project. If included in the attached protocol, please indicate the section.

Our study population consists of 100 sequential members of the community who attend the health clinic at ACCESS. A group of 2-3 medical students will attend the clinic and obtain written consent from participants who fill out our survey on food insecurity and barriers to food access. All data collected from the survey will be completely anonymized from the point of collection and throughout the duration of the research project.

Demographic data will be collected via questions about age, country of origin, years living in the United States, refugee status, education level, proficiency in english, and number of people in the household. We will use the six-question U.S. Adult Food Security and Survey Module to assess food security in households both with and without children. This survey has been previously validated. Additionally, questions regarding food label literacy and acculturation are also used to assess barriers to food. To ensure that participation in this survey is accessible to all members of the community the survey will be translated into both English and Arabic. Survey scores will be assessed and our study population will be analyzed to determine the percentage of households that score positive for food insecurity. Data will then be analyzed by University of Michigan Medical students. Based on survey results, participants will be split into two categories: recent refugees (recent defined as arriving in the US less than 10 years ago) and non-refugees or refugees that have been in the US for greater than 10 years. Level of food insecurity between the two groups will be assessed, p-vaule <0.05 will be considered significant. A qualitative analysis of barriers to food access will also be assessed if food insecurity is present. We hope our results can be used by ACCESS to direct future interventions regarding food and refugees. The results of this study also have the potential for publication.

5-3.4* Describe the subject population for the project.

Inclusion: Any person(s) attending the health clinic at ACCESS and that is at least 18 years or older.

Exclusion: Anyone under the age of 18 years old, persons who are employees at ACCESS.

5-3.5* Will the study involve recruitment and/or participation of subjects in order to produce new data (e.g., surveys, interaction, intervention)?

Yes

5-3.6* How will the study team interact with human subjects?

The study team members will travel to ACCESS where they will interact with members of the community in the waiting room of the health clinic at ACCESS. Team members will then ask potential participants in a face-to-face interaction if they would be interested in participating in a voluntary survey about food insecurity and access.

5-3.7* How will the study team be recruiting subjects?

Subjects who attend ACCESS will be approached by a University of Michigan medical student who will ask the potential participant in a face-to-face encounter if they would be interested in completing a survey about food insecurity and barriers to food access. There will be no patient identifiers asked about and all patient survey responses will remain anonymous.

5-3.8* Describe the setting for the research.

The research interaction will only occur in the waiting room of the health clinic located at ACCESS.

5-3.9* Indicate which of the following established subject pools, if any, will be used for recruitment.

Select all that apply:

N/A

Provide Related UM IRB Project Number or Subject Pool Description:

5-3.10* Indicate which methods will be used for recruitment?

Check all that apply:

Face-to-face contact (e.g. during a health care visit or an interview at a home address, etc.)

If Other, please indicate below:

5-3.11* Risk Level

Click "Add" to enter the risk level associated with this study.

Level Of Risk

View No more than minimal risk

5-3.12* Will the research involve the access, collection, use, maintenance, or disclosure of protected health information (PHI)? PHI is:

- information about a subject's past, present, or future physical or mental health, the
 provision of healthcare to a subject, or payment for the provision of healthcare to a
 subject: AND
- maintained by a HIPAA-covered entity (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).

| 5-3. | 13* Will s | ubjects receive payment or other incentives for their participation in the study? |
|-------|--|---|
| No | | |
| No | | |
| | | |
| 5-3.1 | 11.1 * Wha | at is the level of risk of harm to the subjects resulting from this research? |
| | Risk Level | Description |
| • | No more than minimal risk | A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination. (Note: The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.) Refer to the Risk Grid for more information. |
| 0 | Minor increase over minimal risk | While this risk category may be used to classify research involving adult subject populations, it must be considered in the evaluation of risk in research involving children as defined in 45 CFR 46 sections 404-407*** Risks are more severe than those defined as "No more than minimal risk" and less severe than those described as "Moderate" on the Risk Grid. |
| 0 | Moderate risk | Refer to the Risk Grid for more information. |
| 0 | High risk | Requires scrutiny in regards to the likelihood of direct benefits, and whether or not benefits clearly outweigh risks. Refer to the Risk Grid for more information. |

No

Pre-2018 Exemption Category

Completion of this section is required based on the response provided to question 1-1.1.

12.1* Which of the following exemption criteria applies to the study?

EXEMPTION #2 of the 45 CFR 46.101.(b):

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Pre-2018 Exemption #2/3

This section is read-only and cannot be edited. The section is required based on the response provided to question 12.1.

12-2.1* Does the research involve children as subjects (including subject pool students under age 18)?

No

12-2.1.2* Does the research involve only: educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior?

Yes

12-2.2* Upload tests, surveys and/or interview questions.

| | Name | Version |
|----------|---|---------|
| 9 | Survey- Understanding Refugee Food Access | 0.01 |

12-2.3* Will the research generate information that, if revealed, might place the subjects at risk of personal safety, criminal or civil liability, or damage to their financial standing, employability, or reputation?

No

44. Additional Supporting Documents

44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

| Consent Form 0.01 | | Name | Version |
|-------------------|----------|--------------|---------|
| | 9 | Consent Form | 0.01 |

44.2 Enter any information that should show in a "Supporting Documents" list on the current submission's approval notice, such as document names and version numbers or version dates. Text entered here will AUTOMATICALLY appear word-for-word on the approval letter.

45. End of Application

The form was successfully submitted. Click 'Exit' or 'Finish' to leave the form.