



Memorandum

#11-080

TO: WIC Regional Directors
WIC Local Agency Directors

FROM: Linda Brumble, Unit Manager
Nutrition Education/Clinic Services Unit
Nutrition Services Section

DATE: June 10, 2011

SUBJECT: *Policy No. GA:18.0, Research or Auxiliary Services Involving WIC Participants*

This memo announces revisions to the subject policy as follows. The policy is effective July 1, 2011. At that time it will be posted and you may update your *Policy and Procedures Manual* by accessing the *WIC Website* at: http://www.dshs.state.tx.us/wichd/policy/toc_ga.shtm.

Summary of Revisions

- The request for auxiliary services conducted at local agencies has been incorporated into the policy.
- The Request for *Research or Auxiliary Services from Texas Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Clinics – Application Packet* has been updated to reflect the standardized protocol for applying to the Department of State Health Services (DSHS), State Agency WIC Program and/or DSHS Institutional Review Board (IRB).

If you have any questions or require additional information, please contact Leona Duong, Clinical Nutrition Specialist, at leona.duong@dshs.state.tx.us or (512) 341-4520.

Attachment

<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective July 1, 2011

Policy No. GA:18.0

Research or Auxiliary Services Involving WIC Participants

Purpose

To protect the confidentiality of WIC participants and to ensure that all WIC research and auxiliary services conducted at the local agency (LA) are appropriate and reasonable.

Authority

State Policy

Policy

State agency (SA) approval shall be obtained prior to any research or auxiliary service being conducted at a LA that would involve the use of WIC participants as subjects, the use of WIC participants' records, or any data collection from WIC participants.

Definition

Auxiliary Services – Any outreach or health/educational services provided to WIC participants by nutritional health or social programs, LA's parent organization etc. during the WIC visit.

Research – Any study, investigation, experiment, or survey aimed at the discovery of information or facts, the testing of a hypothesis or theory by external researchers, academic institutions, etc.

Procedure

- I. Any research conducted by LA WIC staff, the LA's parent organization, external researchers, academic institutions, graduate students, etc. intending to use WIC participants as subjects in research projects, shall obtain prior approval from the SA WIC Program. The Request For Research or Auxiliary Services From Texas Special Supplemental

<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective July 1, 2011

Policy No. GA:18.0

Nutrition Program for Women, Infants and Children (WIC) Clinics – Application Packet may be obtained at the WIC State Office – Clinic Services Branch.

- II. Any auxiliary service that involves WIC participants or WIC clinic space shall obtain prior approval from the SA WIC Program. The Request For Research or Auxiliary Services From Texas Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Clinics – Application Packet may be obtained at the WIC State Office – Clinic Services Branch.
- III. If necessary, LAs shall also have the approval of their parent agency prior to any research or auxiliary services being conducted with WIC participants.
- IV. LAs have the right to refuse any research or auxiliary service request if the LA believes it would not be in the best interest of the participants or would be a burden to the LA staff.
- V. If the SA approves the research or auxiliary services, the entity conducting the research may need to submit an application to the DSHS Institutional Review Board (IRB) if deemed necessary by the SA. The DSHS IRB shall approve the research or service before it begins.

**Request For Research or Auxiliary Services From Texas
Special Supplemental Nutrition Program for Women, Children
and Infants (WIC) Clinics**

Applicant Packet

Prepared by:

The Office of Program Decision Support
Division of Family and Community Health Services
Department of State Health Services
1100 West 49th Street
Austin, TX 78756

Prepared for:

The Texas Special Supplemental Nutrition Program for
Women, Infants, and Children
Nutrition Education and Clinical Services Unit
Division of Family and Community Health Services
Department of State Health Services
PO Box 149347
Mail Code 1933
Austin, TX 78714-9347

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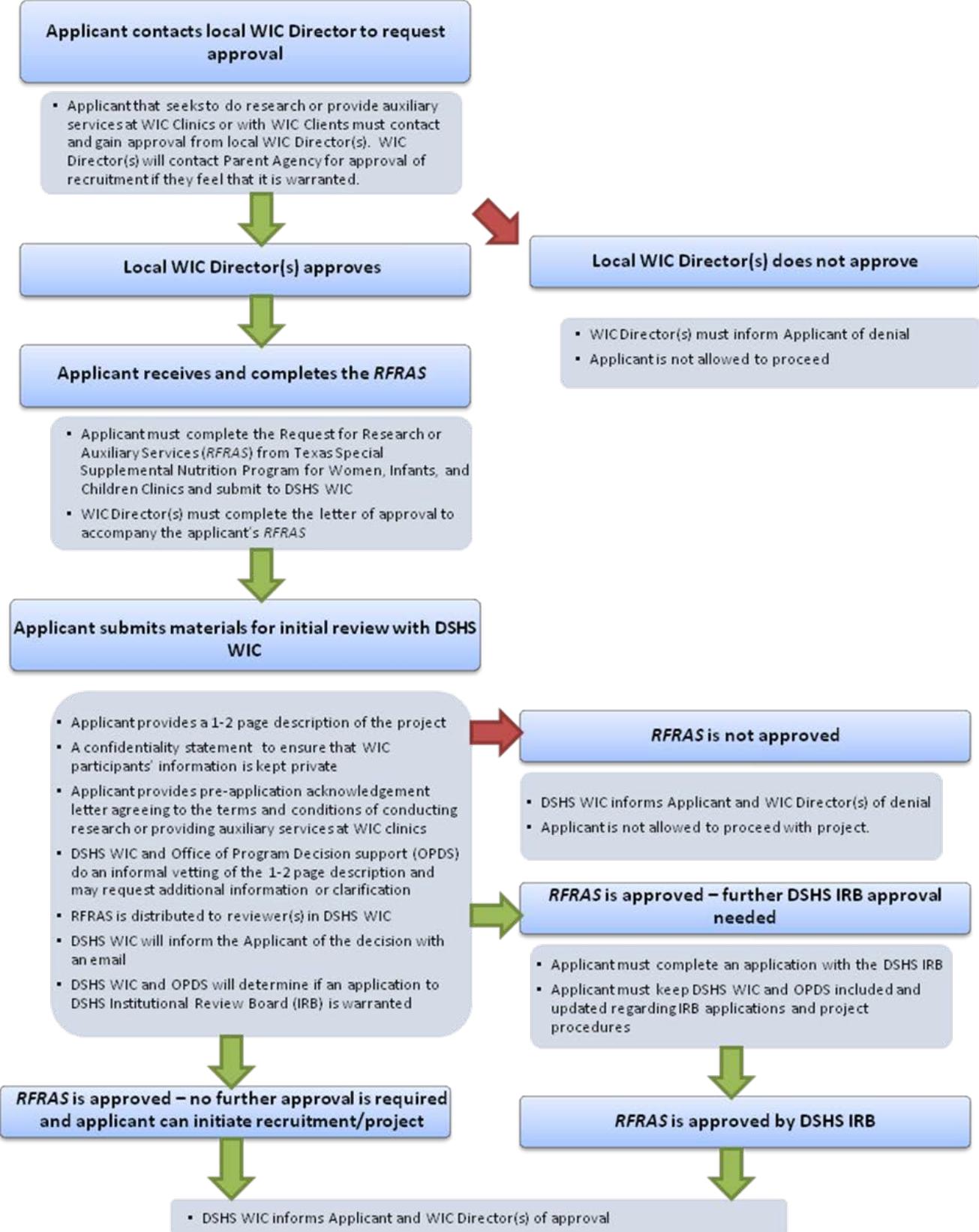
Introduction

The purpose of the *Request for Research or Auxiliary Services* (RFRAS) from Texas Special Supplemental Nutrition Program for Women, Children and Infants (WIC) Clinics Applicant Packet is to provide an orientation to the process of seeking approval from the Texas WIC to recruit participants into research studies. This process is also used to approve the provision of auxiliary service that engages the WIC participants. The packet contains an introduction to the process for applicants, a flowchart of the process for application, a description of how to apply to the Department of State Health Services (DSHS) WIC Program for approval, instructions on applying to the DSHS Institutional Review Board (IRB) for approval, and the final steps after approval by DSHS, WIC and IRB.

The target audience of the packet is any individual who seeks to involve WIC clients for research studies or any agency/individual that wishes to provide auxiliary services that would involve WIC participants. Individuals may belong to entities external to the Texas DSHS such as universities, private non-profit agencies, city or county agencies, or other state agencies. Individuals may also belong to groups internal to DSHS such as regional staff or local WIC agencies.

It is the intent of this packet that individuals seeking to conduct research and auxiliary services involving WIC know the process for seeking approval for these activities at the state level. It also provides a standard process for reviewing requests.

Flowchart of the Process of Obtaining Approval for Research or Auxiliary Services from WIC Clinics



Preparing for a Request For Research or Auxiliary Services from WIC Clinics (Pre-application Phase)

Research or Auxiliary Services

This section describes the steps taken prior to formal request for research and auxiliary services from WIC clinics (pre-application phase). These steps occur at the local agency with the local WIC Director(s) and Parent Agencies. Below is a list of actions applicants conduct at the local level prior to contacting DSHS WIC with a request to use WIC clinic facilities or recruit/interact with WIC participants:

- Contact the local WIC Director(s) of the clinic(s) where recruitment of participants is to take place.
- Provide a brief, 1-2 page description of the proposed study or services to the local WIC Director(s).
- Draft a letter of support from the local WIC Director(s) outlining the study activities and the services. Include clear, bulleted activities that the local WIC Director(s) agrees to (i.e., use of staff time, rooms, or equipment)

The first step in the pre-application phase is to make contact with the local WIC Director(s) from the clinic(s) where recruitment or use of facilities will take place. Recruitment can be for either a research study or to provide auxiliary services. In the event that recruitment occurs at several local agencies, contact with each local WIC Director(s) is necessary. This contact can come in the form of a phone call or e-mail. The purpose of the initial contact is to describe the study or services to the local WIC Director(s) to garner approval at the local level. The local WIC Director(s) will also contact their Parent Agency, if necessary, for approval of the research study or auxiliary service.

Second, provide a 1-2 page description of the proposed study or services to the local WIC Director(s). The purpose of the description is to outline the proposed activities to the local WIC Director(s) so that she/he can determine initial benefit to WIC clients and ensure that activities will not disrupt the flow of the clinic or unnecessarily burden clinic staff. This description should include:

- A brief statement of the purpose of the study or service provision
- A description of the study or services
- The proposed recruitment activities (i.e., flyers posted in the waiting room, announcements made in nutrition education classes, representatives in the waiting room, informational sheet given to WIC clients at certification, etc.)
- A sample of all utilized study or service documents in the appropriate languages for the population that is being served (i.e., forms, sign-in sheets, surveys, pre or post tests, educational handouts, lesson plans for educational sessions, etc.)
- The expected participant sample size
- Any participant information that will be obtained
- A schedule of the days and times when the Applicant will be in the clinic
- Any clinic space or equipment that will be used for the project
- Any involvement of WIC staff members in the project—the number of WIC staff needed, the time commitment expected of each WIC staff member, etc.
- Any reimbursement/contributions to WIC for the collaboration
- The public health impact of the study or services

The project description will also be used in the formal application phase to DSHS WIC.

Third, if the local WIC Director(s) approves the proposed activities or services, the Applicant drafts a letter of support intended to be from the local WIC Director(s) to DSHS WIC. This letter indicates the WIC Director(s)'s terms of the agreement to recruit from her/his clinic. The letter should indicate that the WIC director approves of the proposed study or services as described in the project description.

Research

For research, the Applicant must submit an agreement to the terms and conditions of recruitment from WIC clinics. This agreement states that WIC must provide prior approval of all dissemination activities, including, but not limited to, scholarly journal articles and scientific presentations at conferences.

Additionally, a confidentiality statement is to be submitted by the Applicant. This confidentiality statement must describe the measures being taken to ensure that WIC participants' information are kept confidential. The Applicant should outline the confidentiality safeguards to be employed throughout the study (e.g. maintaining the data on secure, password protected servers; limiting data access only to those individuals directly involved in the study; not releasing data to any other entities; etc.).

A complete list of all applicant activities are included in Appendix A.

Application to the Texas Department of State Health Services WIC (DSHS WIC) to Request for Research or Auxiliary Services from WIC Clinics

Initial review by DSHS WIC

Request for Auxiliary Services

The application phase begins when the Applicant contacts DSHS WIC to inform them of the request for auxiliary services. This contact must be made by e-mail and may be followed-up by phone. Leona Duong is the DSHS WIC contact for these requests (email: Leona.Duong@dshs.state.tx.us). The e-mail to her should include the following:

- Statement of the local WIC Director(s)'s approval for activities
- Attached brief, 1-2 page description of the services
- Confidentiality Statement, if deemed necessary by DSHS WIC

Request for Research

The application phase begins when the Applicant contacts DSHS WIC to inform them of the request for research. This contact must be made by e-mail and may be followed-up by phone. Leona Duong is the DSHS WIC contact for these requests (email: Leona.Duong@dshs.state.tx.us). The e-mail to her should include the following:

- Statement of the local WIC Director(s)'s approval for activities
- Attached brief, 1-2 page description of the study or services
- Attached pre-application acknowledgement letter agreeing to the terms and conditions of recruitment from WIC clinics
- Confidentiality Statement

Vetting by DSHS WIC and/or the Office of Program Decision Support (OPDS)

DSHS WIC staff will vet the proposed activities (i.e., among managers and other staff as necessary). For any requests for research, they may solicit additional review from the Office of Program Decision Support staff (OPDS). Depending on the nature of the request, DSHS WIC staff may ask for more information from the applicant. For example, if the request is for a letter of support from DSHS WIC for a study planned in the future, DSHS WIC may ask for a template of the letter. If the recruitment strategies are not clear or if the letter of support does not detail WIC staff time or resources requested for the research activities, DSHS WIC may seek clarification and ask for a revised letter of support from the local WIC Director(s).

DSHS WIC may have the Applicant contact a staff member of OPDS for additional guidance. Staff at OPDS support WIC and other programs from the Division of Family and Community Health Services in research, evaluation, data management, and data analysis. OPDS assists WIC in processing applications that involve WIC clients in research studies. Staff from OPDS may ask the Applicant more about the recruitment process, how much time WIC staff is involved, whether class time or space is needed, and whether WIC staff is needed for recruitment (i.e., providing information to the client, obtaining informed consent, and/or referring clients to applicant's staff for more information). After review of the materials submitted by the applicant, DSHS WIC and/or OPDS will determine if an application to DSHS Institutional Review Board (IRB) is warranted.

Decision by DSHS WIC on Request For Research or Auxiliary Services from WIC Clinics

DSHS WIC may decide to approve or deny a request. An approval/denial letter will be sent by DSHS WIC staff to the Applicant and the WIC Director to notify them of the approval or denial status of the application. A request can either be approved by DSHS WIC as 1) complete or 2) needing further DSHS Institutional Review Board (IRB) approval. If the approval is complete, the Applicant may initiate the recruitment process. The WIC Director or their designee will observe the research project/auxiliary service within the first two weeks of its implementation and submit a brief summary of their observation to DSHS WIC staff within 1-2 weeks of this observation. If further DSHS IRB approval is needed, the Applicant is to follow the below listed procedures under “Applying to the DSHS IRB after DSHS Approval of Request For Research from WIC Clinics”. OPDS staff will assist the Applicant through the DSHS IRB application process. Upon final approval, the researcher/provider is to provide a status update to DSHS WIC every six months or at the completion of the project, whichever comes first.

Applying to the DSHS IRB after DSHS Approval of Request For Research from WIC Clinics

DSHS IRB Application Specifics

For approved requests for recruitment from WIC clinics, DSHS WIC requires that applicants submit the proposed research study or proposed services (if deemed necessary by DSHS WIC and OPDS) to the DSHS Institutional Review Board (IRB). This ensures that human subjects are protected and the activities pose minimal risk to the client. DSHS WIC requires that applications for research and service delivery be submitted to the IRB to avoid independent judgment of proposed activities. It is the IRB’s authority to review such applications and determine whether the study is exempt or non-research (typical of service delivery projects) or if the study is research and poses minimal risk to the client. The applicant must still apply for and receive approval from the DSHS IRB even if the project has been submitted or approved by another IRB. The IRB approval from an educational institution must be obtained prior to applying to the DSHS IRB. A copy of the educational institution’s IRB approval letter and all of the information that accompanied the application must be submitted as part of the DSHS IRB application.

- The DSHS IRB application can be found at <http://www.dshs.state.tx.us/irb/applirb.shtm>.
- The DSHS IRB Frequently Asked Questions can be found at <http://www.dshs.state.tx.us/irb/Frequently-Asked-Questions/>

Applicants must complete all required forms (Application and Initial Submission Detail) listed under the section “New Application,” along with any optional form that may be applicable to their study (i.e. Request for Exemption from Review of Research, Request for Expedited Review of Research, Waiver of Informed Consent Request). The application form, the exempt form, and the expedited form require original signatures; electronic signatures are acceptable. Applicants will receive instructions on completing the DSHS contacts on the application form.

When completing the application, the recruitment strategy and the consent form require special consideration by the applicant. The recruitment strategy should specify whether and how much WIC staff time is used, what the function of the WIC staff is, if they are necessary during recruitment, whether class time or space is needed, and whether WIC equipment will be used. Typically use of WIC staff time for any aspect of the recruitment is prohibited, especially if that time involves conducting informed consent.

Consent forms must include several important elements. They must include wording clearly stating that participating in the study or by receiving the services offered in no way impacts past, current, or future

receipt of clients' WIC benefits. Consent forms must also state that not taking part in the study or receiving services and leaving the study or refusing services will not affect past, current, or future WIC benefits. The applicant must include a statement indicating that WIC will not pay for costs associated with emotional or physical problems as a result of participation. Finally, the Applicant must confirm that the consent form is composed at a 6th to 8th grade reading level prior to submission.

The application must include all forms and documents the client completes or receives as part of the research study or in order to receive services. This includes but is not limited to consent form, assent form for minors, surveys or questionnaires, informational sheet, list of data collected from clients, and flyers used for recruitment.

Items Not Listed in the Application

The DSHS IRB has historically requested two additional items not indicated in the application. The first is evidence of human subject's protection training. Online certification can be found at <http://phrp.nihtraining.com/users/login.php>. The certificate can be saved electronically and submitted with the protocol for the study or service delivery. Second, if non-English versions of the consent form or recruitment materials (i.e., informational sheets or flyers) are to be used, the DSHS IRB requests evidence of the translator's credentials. Both of these items should be included in the Appendix of the protocol. It is recommended that all materials are available in both English and other relevant languages (i.e., Spanish) depending on the target population.

Next Steps: What Happens After DSHS IRB Approval?

DSHS IRB approval can take between two weeks and three months. The Principal Investigator named on the application page and all DSHS contacts will receive electronic notification when the study or proposed service delivery is approved. This notification will contain the text of the approval letter. After copies of the letter are made, the original will be sent to the Principal Investigator. All IRB approval letters will include a statement indicating that the Principal Investigator must contact the DSHS IRB before any changes to the study or proposed service delivery is implemented. The IRB decision will also be forwarded to the local WIC Director(s).

The purpose of the letter is to document DSHS IRB approval and final stipulations of the agreement to recruit from WIC clinics. It includes a brief summary of the purpose of the research study or service delivery, the recruitment strategy, and the timeframe for activities (i.e., start and end dates). Finally, it includes a statement indicating that study results (e.g., final report, survey results, or executive summary) will be shared with WIC.

Appendix A: Applicant Checklist

	Contact and gain approval from Local WIC Director(s) and Parent Agencies (if necessary)
	Contact DSHS WIC for Request For Research and Auxiliary Service application (<i>RFRAS</i>)
	Provide brief, one page summary of research or auxiliary services
	Provide draft letter of support to Local WIC Director(s)
	Submit Local WIC Director(s) letter of support
	Provide the pre-application acknowledgement letter agreeing to the terms and conditions of recruitment from WIC clinic – applies to research only
	Confidentiality Statement – applies to research only