

# **FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)**

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**TITLE OF INFORMATION COLLECTION:** Assessment of a Pharmacist-Led Transitions of Care Service Utilizing an Admissions Enhanced, Patient Risk Evaluation Approach: the ICARE Program

## **DESCRIPTION OF THIS SPECIFIC COLLECTION**

### **1. Statement of need:**

The goal of having a transitions of care (TOC) service team is to prevent hospital readmissions by focusing on TOC programs aimed at high-risk patients who have a history of multiple hospital admissions. The TOC team uses an ICARE (**I**dentify at admission, **C**ounsel before discharge, secure **A**ccess to medications, **R**each out for follow up, **E**ngage community providers) approach where they help ensure continuity of care as the patient moves between care settings for patients at highest risk for hospital readmission. The TOC team is composed of physicians, pharmacists, social workers, and quality improvement nurses. This pharmacist-lead TOC team will manage a cohort of patients from admission through post-discharge period to remove barriers to care, decrease the risk for medication-related harm, and ensure the continuity of care through collaboration with community providers.

The FDA Safe Use Initiatives has the goal of reducing preventable harm from medications. This project falls in the scope to reduce preventable harm in a high-risk and vulnerable population.

### **2. Intended use of information:**

We will use the data collected from the following anonymous surveys to further understand the perception of currently offered services and the demand for expanded services through survey outcomes: (1) pre-implementation provider perception and demand survey (baseline survey); and (2) implementation survey (provider acceptability, impact, and satisfaction) conducted at 12 months and 18 months from the baseline survey.

Previous studies have examined the impact of the programs on outcomes related to the state of specific diseases.

### **3. Description of respondents:**

Respondents to this information collection are outpatient providers who will be part of the TOC model who will facilitate communication and collaboration with the TOC team. The anonymous surveys will be distributed to physicians, nurse practitioners, physician assistant, social workers, medical assistants, nurses, and others who provide care to patients in the hospital.

The TOC group plans to conduct several surveys (pre-implementation/baseline survey and 12-month, and 18-month surveys) with up to 150 people. The surveys will evaluate provider perception and provider demand evaluations of this TOC program and will help assess provider attitudes, use, and satisfaction towards the TOC program.

**4. Date(s) to be conducted:**

The research contract is effective from 8/12/2021 to 11/12/2023. However, the research team will not begin their surveys until the Food and Drug Administration receives Office of Management and Budget approval for the information collection.

**5. Project timeline:**

- a. At the beginning of this project, the Pre-implementation Provider Perception and Demand Evaluation survey will be disseminated.
  - i. The survey will be disseminated one time during the project period. The goal is to collect information about TOC services before implementing this project.
- b. The 3-month, 6-month, 12-month evaluations and final evaluations are not survey-based. Program information and clinical data will be assessed at each of these time points.
  - i. This is data to which most of the referenced statistical methods will be applied.
- c. The 12-month and 18-month provider surveys will be disseminated to providers.
- d. These surveys will be disseminated two times during the project period. The goal is to evaluate provider impact on and experience with the TOC service.

**6. How the information is being collected:**

Recruitment at East Alabama Medical Center (EAMC) will occur at regular provider meetings. All meeting participants will be verbally invited to complete the anonymous survey. The contracted TOC group will invite physician assistant, social workers, medical assistants, nurses, and others who provide care to patients in the hospital to participate. Surveys will be sent electronically through Auburn University's Clinical Health Service Qualtrics platform. The survey will be delivered via online platform. Recruitment will take place at EAMC.

At present, COVID-19 has not impacted our communication and recruitment plan. Furthermore, we do not anticipate COVID-19 to impact our operations because hospital providers are still meeting in person.

**7. Confidentiality of respondents:**

The survey is anonymous and voluntary. No personally identifiable information will be collected. A participant can withdraw by either not completing the survey or exiting out of the browser window. Their decision to not participate will not jeopardize future relations with Auburn University.

8. **Amount and justification for any proposed incentive:**

No incentives will be provided for completing the survey.

9. **Questions of a sensitive nature:**

The questions in the surveys are not sensitive in nature. Questions vary from requesting the profession of the participant to inquiring about their thoughts about the TOC team.

10. **Description of statistical methods:**

No statistical methods are needed for the surveys.

**BURDEN HOUR COMPUTATION:**

Type/Category of Respondent	No. of Respondents	Number of Responses per Respondent	Participation Time	Burden (hours)
Outpatient Providers at EAMC	150	3	.083 hours (5 minutes)	37.5

**REQUESTED APPROVAL DATE:** February 2022

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