

SECTION 2: COMPREHENSIVE DIALYSIS STUDY (CDS) PATIENT ENROLLMENT AND SCREENING DOCUMENTS

IN SECTION 2 OF THE MANUAL OF OPERATIONS YOU WILL FIND COPIES OF ALL RECRUITMENT AND SCREENING MATERIALS INTENDED TO BE USED WITH THE COMPREHENSIVE DIALYSIS STUDY.

THE TITLE OF THE DOCUMENT AND A BRIEF DESCRIPTION OF ITS INTENT IS PROVIDED BELOW.

CDS Patient Enrollment Process

The CDS Patient Enrollment Process document is intended to provide reviewers with a brief description of the CDS patient enrollment process.

CDS Informed Consent QOL (English/Spanish)

The Informed Consent is intended to: (1) inform the CDS participants of the content of the Comprehensive Dialysis Study (Quality of Life); and (2) to gain individual consent based upon an appreciation and understanding of the Comprehensive Dialysis Study (Quality of Life). The CDS Informed Consent QOL is to be included in all CDS QOL packets and should be mailed out to all potential QOL participants.

CDS Informed Consent QOL/Nutrition (English/Spanish)

The Informed Consent is intended to: (1) inform the CDS participants of the content of the Comprehensive Dialysis Study (Quality of Life/Nutrition); and (2) to gain individual consent based upon an appreciation and understanding of the Comprehensive Dialysis Study (Quality of Life/Nutrition). The CDS Informed Consent QOL/Nutrition is to be included in all CDS QOL/Nutrition packets and should be mailed out to all potential QOL/Nutrition participants.

CDS Patient Bill of Rights (English/Spanish)

The purpose of the Bill of Rights is to ensure the ethical treatment of every CDS participant who is asked to take part in the research study. Without exception, all persons in all settings are entitled to receive ethical treatment. The CDS Patient Bill of Rights is to be included in all CDS packets and should be mailed out to all potential CDS participants.

CDS QOL/Nutrition Patient Questionnaire and Human Activity Profile

The QOL/Nutrition Patient Questionnaire and Human Activity Profile is used to obtain patient-reported data. The document contains 94 questions and is used to obtain information relating to general health, physical activity, and health-related quality of life from each participant at the time of the baseline screening.

Block 2000-Brief Food Questionnaire

The Block 2000-Brief Food Questionnaire is used to obtain patient-reported data. The document contains a total of 105 questions and is used to obtain information relating to dietary health, and nutrition.

Food Frequency Form

The Food Frequency Form is intended to help CDS nutrition participants identify or picture a variety of serving or portion sizes while completing the Block 2000-Brief Food Questionnaire. The Food Frequency Form is to be included in all CDS QOL/Nutrition packets and should be mailed out to all potential QOL/Nutrition participants.

CDS Dear Dialysis Facility/Medical Director Letter

The Dear Dialysis Facility/Medical Director Letter is intended to notify the Dialysis Facility and the Medical Director that their dialysis facility was selected to participate in the CDS. In addition, the letter briefly informs the recipient of the study's purpose and what is being asked of them/their clinic. The CDS Dear Dialysis Facility/Medical Director Letter is to be sent out to each participating dialysis facility with each CDS mailing.

CDS Dear Colleague Letter QOL/Nutrition

The Dear Colleague Letter QOL/Nutrition's purpose is to notify the CDS contact at each of the Nutrition dialysis facilities that materials for the CDS are enclosed. In addition, the letter also provides a brief set of directions for the recipient to follow and complete. The Dear Colleague Letter is to be sent out to each participating dialysis facility with each CDS Nutrition mailing.

CDS Patient Invitation Letter (English/Spanish)

The Invitation Letter is intended to be used to invite individuals who have started dialysis during the past six months to participate in the CDS. The letter also notifies the individual that they have no obligation to actually participate in any study, and that they may withdraw permission to be contacted at any time. The CDS Patient Invitation Letter is to be included in all CDS packets and should be mailed out to all potential CDS participants.

CDS Participant Availability Form

The CDS Participant Availability Form is intended to be completed by the dialysis center staff. The form provides important information relating to individual availability and contact information and is required to collect data if an individual is not able to respond on his/her own. The Participant Availability Form is to be mailed to each potential participant's dialysis facility.

CDS Participant Information Form (English/Spanish)

The CDS Participant Information Form is intended to gather current contact information, participant availability, language preference, and information about participant status. This document is to be included in all CDS packets and should be mailed out to all potential CDS participants.

CDS Instruction Sheet QOL (English/Spanish)

The CDS Instruction Sheet QOL provides a simple set of directions for the potential participant to notify the CDS Coordinating Center regarding interest in participating in the CDS. This document is to be included in all CDS QOL packets and should be mailed out to all potential CDS QOL participants.

CDS Instruction Sheet QOL/Nutrition (English/Spanish)

The CDS Instruction Sheet QOL/Nutrition provides a simple set of directions for the potential participant to notify the CDS Coordinating Center regarding interest in participating

in the CDS. This document is to be included in all CDS QOL/Nutrition packets and should be mailed out to all potential CDS QOL/Nutrition participants.

CDS Participant Thank You Letter – Study Closed

The CDS Participant Thank You Letter is to be mailed out to any consenting participant who agreed to take part in the CDS after the study has closed. The letter thanks the individual for his or her interest and notifies him or her that the CDS is no longer enrolling participants.