

## **Background**

OMB approved ICR# 0920-0741 in June of 2007. During a series of conference calls with OMB, CDC informed OMB that the title of the ICR would be changed from CADDRE to SEED. As discussed during these conference calls, there was a consensus amongst several collaborating clinicians that the SEED title is more inclusive of the respondent universe - children with and without developmental disabilities. The name CADDRE, on the other hand, centered on just one group within the sample population (the CASE group/children with autism) and there was concern that the limited focus might become a potential barrier for our recruitment purposes. This name change was also documented on the final page of the revised supporting statement sent to, and approved by, OMB.

Note Regarding Title of ICR:

The title of this ICR has changed from the National CADDRE Study: Child Development and Autism to the Study to Explore Early Development (SEED). Pending OMB approval, CDC will submit a change request to implement this change.

While the formal name change from CADDRE to SEED is the primary purpose of this change request, we would also like to propose minor changes to the study brochure and one of the study questionnaires (as discussed below).

## **Summary of forms being submitted with OMB form 83-C**

We are submitting the following changes with the OMB 83-C Form:

- (1) The following changes are being made to the documents listed below.

<b>APPENDIX</b>	<b>DOCUMENT NAME</b>	<b>CHANGE/ EDIT</b>
B.1	CGI script	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.1	Enrollment letter	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.2	Yellow folder instructions	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.3	Consent Form	1. Changed name of study from CADDRE to Study to Explore Early Development (SEED) 2. Deleted word 'non-identifiable' on pg. 7
E.4	Clinic Visit Prep Guide	Changed name of study from

		CADDRE to Study to Explore Early Development (SEED)
E.5	CGI Prep Guide	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.8	Study Bill of Rights	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.9	Autoimmune Survey	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.12	GI Questionnaire	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.15	Paternal Occupational Hx	Formatting changes (i.e. indent, deletions, etc). Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.18	HIPAA letter & medical release forms	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.19	How to Collect Cheek Cell Samples	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.20	Buccal Consent	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
E.21	Cheek Swab Transmittal Form	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
F.3	STQ	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
H.1	Diet Diary	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
H.2	Stool Diary	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
H.3	Diet Diary Measuring Guidelines	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
M.1	Intro letter	Changed name of study from CADDRE to Study to Explore Early Development (SEED)

M.2	Brochure	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
M.3	Response card	Changed name of study from CADDRE to Study to Explore Early Development (SEED)
M.4	Poster	Changed name of study from CADDRE to Study to Explore Early Development (SEED)

- (2) Additionally, the text of the SEED brochure is being modified for the purposes of formatting consistency. The revised brochure is currently being formatted; the final, formatted version will be sent to OMB upon completion. See Attachment
- (3) The Paternal Occupational Questionnaire (Appendix E.15) is being revised to include further clarifications for instructional purposes as well as formatting consistency. See Attachment