CJ-DATS Steering Committee

Step'n Out Study: Interim Report

Through November 30, 2006

Prepared for:

NIH-NIDA/DSMB

Prepared by:

The Step'n Out Team

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And

The CJ-DATS Steering Committee

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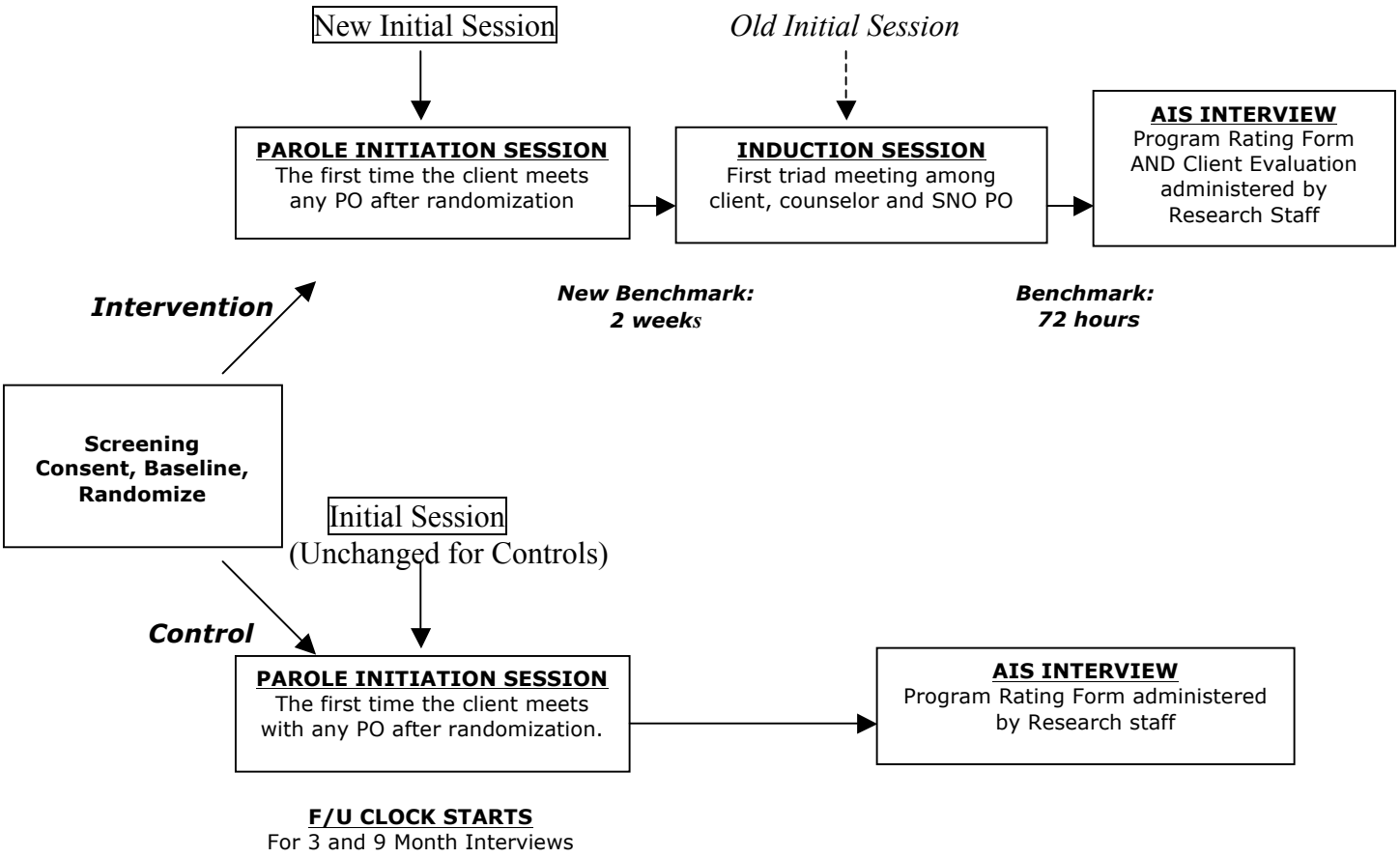
Introduction

In a letter dated November 1, 2006, NIDA expressed specific concerns about the ongoing viability of the Step'n Out study. NIDA recommended:

1. Research procedures that introduce bias confounded with a study arm must be modified to eliminate or minimize such bias. For example, random assignment to a study arm that requires a change in PO or a delay in intake/assessment may need to be changed. Sites that cannot implement changes to reduce differential bias should be dropped.
2. Imbalances between the control arm and experimental arm of the experiment are troubling. Some of this imbalance results from differences in the attractiveness of the experimental intervention, but some may be a consequence of adherence definitions. For the latter, the definition of adherence might be reconsidered so that procedural imbalances can be reduced…However it is decided to deal with this issue, imbalances in participation between the control arm and experimental arm must be addressed and reduced.
3. The organizational barriers to implementation must be measured. These measures include capturing data related to issues such as length of time to first interview; length of time to second interview; content of interviews; number of subject-system (parole and addiction treatment) contacts in set time frames; scheduling process data (times scheduled/rescheduled/number of "failure rates" of appearances and whether subject, PO, or treatment counselor related), etc.

FIGURE 1



In response to NIDA Concerns #1 and #2 that study procedures and definitions are introducing systematic bias and baseline imbalances, the SNO investigators implemented in early November a significant change in the definition of the Initial Session for the intervention arm of the study *(Figure 1*). The definition for the Initial Session had previously been different for each of the two study groups. For the intervention group, the Initial Session was originally defined as the Induction Session (the triad meeting with the client, parole officer and treatment counselor). This Induction Session, because of the participation of the counselor, often took a longer time to

arrange than a regular meeting between client and parole officer. Moreover, it was usually not the first time the client met with a parole officer post-randomization. In response to NIDA's concerns about this disparity in definitions, and its consequences for differential inclusion of subjects in the intervention and control conditions, as well as to acknowledge the realities of the parole process, the Initial Session for intervention subjects has been redefined as the first meeting a subject has with a parole officer post-randomization, for which the term "Parole Initiation Session" (or informally "Touch Base Session") has been adopted. In most cases this session is the parole intake and initial assessment session. In keeping with the events of the parole process, the Parole Initiation session may or may not involve the Intervention PO. We will monitor the extent to which this session occurs with a PO other than the assigned Intervention PO. Regardless, this major study modification equilibrates the scheduling of the Initial Session between the intervention and the control group. This change has been retrospectively and prospectively applied to data collected with regard to study inclusion and follow-up rates. It has not been retrospectively applied to timeliness of follow-up. As this report will demonstrate, the change of the Initial Session for the intervention group to the Parole Initiation Session is intended to decrease imbalance in study participation between the study conditions even though it may also have the effect of decreasing effect size.

Regarding NIDA's Concern #3, SNO sites collect information regarding organizational barriers to implementation. Much relevant information on the working environment and satisfaction is available from the parole officers (Index of Interdisciplinary Collaboration, Interorganizational Relationships and Probation and Parole Strategies Questionnaires at baseline and 12-months) and treatment counselors (same as POs plus TCU Survey of Organizational Functioning) instrumentation. The Program Rating Form (Part of the AIS and 3-month Interviews) assesses domains important to clients' satisfaction with parole and treatment. Parole adherence is readily available for intervention subjects, but the SNO investigators have purposely tried to limit intrusion into usual parole. That said, we will examine parole records for date of first contact and second contact, as well as number of contacts in the first three months. The SNO investigators will also investigate whether data regarding scheduling, etc. is retrievable and reliable. Contacts with the treatment system will be available from client reports on the 3-month interview. This information will also allow evaluation of "compliance" among control subjects. Of note, we also have qualitative information on implementation from focus groups with POs and counselors. An early manuscript will be developed based on this qualitative information.

The DSMB, in its letter of November 17, 2006 based on their analysis of data through August 31st, indicated it had continuing serious concerns about the Step 'n Out experiment. In his email of November 19, the DSMB Chair provided very helpful and specific clarification regarding these concerns. The DSMB recommended that the SNO study team and Steering Committee:

1. perform interim analysis on the data available within 30 days from the date of this letter and report on whether there is any evidence of a small or moderate effect size on the planned outcomes or any outcome.
2. provide Mr. Tim Moore of AMAR International with a matching dataset and syntax so that he can replicate these analyses for the DSMB.
3. delay any site start-up until the interim analysis is done.
4. work on developing text for how to best report the problematic recruitment and follow-up.
5. Unless at least a small effect size (d=.2) is found in the experiment (and assuming follow-up improvements continue), the DSMB recommends stopping recruitment, finishing the follow-up of existing cases, and salvaging what you can from this as an observation study of re-entry.

Regarding DSMB Recommendation #1, much of the remainder of this document reports the results of the interim analysis on the first 36% of the projected sample who reached the 3-

month follow-up as of November 30th. As noted in the Steering Committee's letter of December 12th, the data required cleaning. As the current report will demonstrate, data cleaning, especially addressing outliers that were mentioned in the AMAR report, along with changes in the definition of the Initial Session for the intervention group (as described above) have helped to attenuate the imbalance in study conditions. Another change from AMAR's previous analysis is that the current report is based on all available data from the Timeline Follow Back (TLFB) CJ-DATS Follow-up Form, as well as urine toxicology data through November 30, 2006. As described in the Steering Committee letter of December 12th, if the interim analyses and case flow suggest that:

(a) dropout before the Initial Session was not-at-random;
(b) none of the primary outcomes has any potential to produce an effect size that will be small or larger; or
(c) recruitment will be insufficient to provide power to detect a small or larger effect for any of the primary outcomes at conventional levels.

then the Steering Committee would begin the process of converting this study to a quasi-experiment. If the analyses suggest that a, b, & c are all untrue, then the Steering Committee would request a conference call with NIDA and the DSMB to discuss whether the new information might allow for less radical changes in the design.

Regarding DSMB Recommendation #2, the Coordinating Center delivered the updated and cleaned data with analytic syntax to Mr. Moore at AMAR through the CJ-DATS website on December 22nd to allow independent verification and interrogation of the data.

DSMB Recommendation #3 is not possible: all sites have begun recruitment. The SNO investigators initiated those sites in response to earlier concerns about recruitment rates. To stop those sites would guarantee that recruitment would be insufficient to meet planned study objectives. It would also damage good relations with criminal justice and addiction treatment partners with whom we have executed contracts. The Steering Committee has supported keeping all sites open until a final decision has been made regarding final status of the study.

Table 1: Recruitment History

Site	Initial Recruitment Strategy	Revised Recruitment Strategy	Avg. Monthly Numbers (7/06 to 11/06)
RI	Recruited in prison – found majority of subjects were flattening in prison and being released without parole conditions	Recruit EMP population beginning in July 2006 – know this population will be released with parole conditions	3 achieving IS
DE	Recruited in prison – found large portion of subjects violated in halfway house or not eligible for aftercare and no longer eligible for the study	In June 2006, got permission from CJ system to begin recruitment at parole intake – number of those not reporting for parole decreased	8 achieving IS
CT	Recruited at parole office from referrals from the addiction treatment staff – no post-randomization ineligibles but fairly small case flow	Opened second site at Hartford parole office in November 2006	2 achieving IS
VA	Recruited at parole office both at intake and from parole officer referrals – found some subjects would still be ineligible after randomization	Currently doing file reviews of all new intakes and receiving referrals from treatment personnel	7 achieving IS
OR (UCLA)	Recruited at parole office – flow of subjects was inadequate	In May 2006, began recruitment at 2 prisons in the state where other projects have had success	2 achieving IS

Regarding DSMB Recommendation #4, full follow-up interviews are attempted on all subjects who reach the Initial Session with the parole officer. Because of the nature of the parole and prison system, a significant portion of the population that was randomized in prison (especially in Delaware) never got released, violated parole in the halfway house before beginning the study, or got transferred out of the parole office where the study is being conducted. Changes in recruitment practices at each site (Table 1) have been employed to address adherence concerns, and this has led to a diminution in the number of post-randomization ineligibles in recent months. The inclusion of subjects who had "Parole Initiation" dates has further attenuated this effect.

Recruitment and the Initial Session

Table 1 summarizes historic and current recruitment practices at each site, along with the average monthly number of subjects making the Initial Session each month from July through November 2006. Recent recruitment data suggest that a minimum of 20 subjects per month will make the Initial Session.

Full follow up interviews are done on subjects who reach the Initial Session with the parole officer. Because of the nature of the parole and prison system and initial recruitment strategies, there was a significant portion of the randomized population that did not make it to a first parole session. Reasons for this include never being released from prison, violating parole in the halfway house before beginning the study, and being transferred out of the parole office where the study is being conducted. Changes in recruitment practices at each site have decreased this number in the last quarter, as can be seen in the data in Table 2.

Table 2: Randomized Subjects who have not Made the Initial Session by Quarter

Time Period	Number of those not reporting for Parole
January to June 2005	7
July to December 2005	41
January to June 2006	41
July to November 2006	2

One concern raised by NIDA and the DSMB focused on the imbalance in the number of subjects in each study arm reaching the Initial Session. Data reported through August 31, 2006 had shown that 183 subjects had completed the Initial Session, with 106 (58%) in the control group and 77 (42%) in the intervention group. As described in the Introduction, the Initial Session for the intervention group has been changed back to the Parole Initiation date, which is now the same initial contact with the parole system for both study conditions. Data on Parole Initiation dates has been gathered from the sites. Table 3 presents the Initial Session numbers through 11/30/2006 using the Parole Initiation dates. Of 286 subjects who made the Initial Session, 144 (50.3%) are controls and 142 (49.7%) are intervention. Baseline data for this report are missing for sixteen of these subjects because of pending corrections and completions.

Table 3
Disposition of All Subjects Randomized by Center and Overall
All Contacted Subjects through 11/30/2006

		Study Condition					
		Not Randomized		Randomized to Control		Randomized to Intervention	
		Count	%	Count	%	Count	%
Total Subjects		31	100.0%	200	100.0%	200	100.0%
Research Site	Virginia	22	71.0%	32	16.0%	35	17.5%
	Connecticut - Bridgeport	8	25.8%	33	16.5%	30	15.0%
	Delaware	0	.0%	102	51.0%	103	51.5%
	Oregon	0	.0%	27	13.5%	26	13.0%
	Rhode Island	0	.0%	6	3.0%	6	3.0%
	Connecticut – Hartford	1	3.2%	0	.0%	0	.0%
Subject status	Had Parole Initiation session	0	.0%	144	72.0%	142	71.0%
	Parole Initiation session pending	0	.0%	13	6.5%	12	6.0%
	Will Not Have Parole Initiation session	0	.0%	43	21.5%	46	23.0%
	Ineligible, not randomized	31	100.0%	0	.0%	0	.0%
Ineligibility - Screening	Did not meet age criteria - pre-randomization	0	.0%	0	.0%	0	.0%
	Did not meet TCU drug screen critieria - pre-randomization	25	83.3%	0	.0%	0	.0%
	Did not LCFS criteria - pre-randomization	11	36.7%	0	.0%	0	.0%
	Did not meet SCID criteria - pre-randomization	0	.0%	0	.0%	0	.0%
	Did not speak English - pre-randomization	0	.0%	0	.0%	0	.0%
	Parole conditions limited participation - pre-randomization	4	13.3%	1	100.0%	0	.0%
	Did not express understanding of study – pre-randomization	1	3.3%	0	.0%	0	.0%
Reason for not reporting for parole	no aftercare	0	.0%	2	1.0%	2	1.0%
	violated parole, back to prison	0	.0%	33	16.5%	26	13.0%
	transferred to other parole office	0	.0%	5	2.5%	3	1.5%
	maxed out in prison/no time	0	.0%	2	1.0%	11	5.5%
	sex offender	0	.0%	1	.5%	0	.0%
	other post-randomization ineligible (specify)	0	.0%	0	.0%	1	.5%
	Absconded	0	.0%	0	.0%	2	1.0%
	refused or voluntary withdraw	0	.0%	0	.0%	1	.5%
	Not applicable, parole report pending, complete, or unknown	31	100.0%	157	78.5%	154	77.0%

Baseline Characteristics

Tables 4, 5, and 6 present updated baseline characteristics for those completing the Initial Session by study condition. Table 5 presents descriptives for criminal justice variables collected on the CJ-DATS Intake for the period prior to the arrest that led to the most recent incarceration. In the data that were sent to the DSMB for the November meeting, there were some incorrect outliers for a number of these variables, including number of days in jail last 6 months, number of times arrested last 6 months, and number of lifetime arrests. These have been corrected in the current dataset.

Table 4
Summary of Demographics
Subjects Randomized and Completing Initial Session (i.e. Parole Initiation Session) through November 30, 2006

	Control (Randomized)		Control (Parole Initiation)		Intervention (Randomized)		Intervention (Parole Initiation)	
	Count	**%**	**Count**	**%**	**Count**	**%**	**Count**	**%**
Total Subjects	200	100.00	144	100.00	200	100.00	142	100.00
Male	168	84.00	119	82.64	172	86.00	119	83.80
Female	32	16.00	25	17.36	28	14.00	23	16.20
Race/Ethnicity								
Hispanic/Latino/a	23	11.68	18	12.77	21	10.55	19	13.48
African American/Black Race	104	52.79	78	55.32	105	52.76	76	53.90
White Race	73	37.06	46	32.62	74	37.19	47	33.33
Asian Race	3	1.52	3	2.13	1	0.50	1	0.71
Pacific Islander Race	2	1.02	2	1.42	3	1.51	2	1.42
Native American Race	4	2.03	4	2.84	4	2.01	4	2.84
Other Race	15	7.61	13	9.22	15	7.54	14	9.93
Research Site								
Virginia	32	16.00	28	19.44	35	17.50	29	20.42
Connecticut - Bridgeport	33	16.50	32	22.22	30	15.00	28	19.72
Delaware	102	51.00	59	40.97	103	51.50	60	42.25
Oregon	27	13.50	20	13.89	26	13.00	20	14.08
Rhode Island	6	3.00	5	3.47	6	3.00	5	3.52
	Mean	**Std. Dev**	**Mean**	**Std. Dev**	**Mean**	**Std. Dev**	**Mean**	**Std. Dev**
Age	33.39	8.59	33.58	8.23	33.25	8.72	33.95	8.38

Table 5
CJ Baseline Characteristics
Subjects Randomized and Completing Initial Session (i.e. Parole Initiation Session) through November 30, 2006

		Control (Randomized)	Control (Parole Initiation)	Intervention (Randomized)	Intervention (Parole Initiation)
# Times Arrested Lifetime	Valid N	188	136	184	133
	Mean	13.2	10.9	13.5	14.3
	Median	8	8	10	9
	Minimum	0	0	1	1
	Maximum	250	50	150	150
	Std Deviation	24.2	9.2	16.3	18.3
	25th Percentile	5	5	6	6
	75th Percentile	12	13	15	15
# Times in Jail Lifetime	Valid N	190	138	184	133
	Mean	8.5	8.1	10.5	11.5
	Median	5	5	6	6
	Minimum	0	0	1	1
	Maximum	100	100	150	150
	Std Deviation	11.1	11.01	15.8	17.7
	25th Percentile	3	2.75	4	4
	75th Percentile	10	10	10	11.5
Total Time in Jail Lifetime (Months)	Valid N	188	136	183	132
	Mean	57.8	60.8	62.7	66.9
	Median	38	38.5	42	48
	Minimum	0	2	1	1
	Maximum	360	360	360	240
	Std Deviation	56.2	60.2	57.9	57.4
	25th Percentile	21.25	21	23	25
	75th Percentile	75.25	81.75	84	93
# Times Arrested Past 6 Mos	Valid N	189	137	184	133
	Mean	1.5	1.5	1.2	1.3
	Median	1	1	1	1
	Minimum	0	0	0	0
	Maximum	16	16	11	11
	Std Deviation	1.8	1.7	1.1	1.3
	25th Percentile	1	1	1	1
	75th Percentile	1	2	1	1.5
# Times in Jail Past 6 Mos	Valid N	189	138	184	133
	Mean	0.86	0.74	0.73	0.71
	Median	1	1	1	1
	Minimum	0	0	0	0
	Maximum	12	6	10	10
	Std Deviation	1.3	1.0	1.0	1.1
	25th Percentile	0	0	0	0
	75th Percentile	1	1	1	1
# Days in Jail Past 6 Mos	Valid N	186	136	182	133
	Mean	14.5	12.9	15.3	18.4
	Median	0	0	0	0
	Minimum	0	0	0	0
	Maximum	180	180	180	180
	Std Deviation	35.1	33.7	38.5	40.6

		Control (Randomized)	Control (Parole Initiation)	Intervention (Randomized)	Intervention (Parole Initiation)
	25th Percentile	0	0	0	0
	75th Percentile	2.25	2	0.25	3
# Times Arrested Past 30 Days	Valid N	189	137	184	133
	Mean	0.86	0.85	0.82	0.82
	Median	1	1	1	1
	Minimum	0	0	0	0
	Maximum	7	4	6	6
	Std Deviation	0.72	0.61	0.68	0.68
	25th Percentile	1	1	0	0
	75th Percentile	1	1	1	1
# Days in Jail Past 30 Days	Valid N	188	136	182	131
	Mean	1.10	1.24	1.81	2.27
	Median	0	0	0	0
	Minimum	0	0	0	0
	Maximum	30	30	30	30
	Std Deviation	4.53	4.84	5.87	6.67
	25th Percentile	0	0	0	0
	75th Percentile	0	0	0	0

Table 6a
Summary of SA History- Baseline
Subjects Randomized and Completing Initial Session (i.e. Parole Initiation Session) through November 30, 2006

		Control (Randomized)		Control (Parole Initiation)		Intervention (Randomized)		Intervention (Parole Initiation)	
Total Subjects with Completed Baselines		188	100.00	136	100.00	184	100.00	133	100.00
#1 Most Serious Drug Before TX	none	1	0.53			2	1.09	2	1.50
	alcohol	39	20.74	24	17.65	30	16.30	21	15.79
	tobacco	22	11.70	16	11.76	11	5.98	11	8.27
	marijuana	29	15.43	21	15.44	26	14.13	21	15.79
	hallucinogens	1	0.53	1	0.74	5	2.72	4	3.01
	crack	36	19.15	25	18.38	33	17.93	21	15.79
	cocaine	7	3.72	5	3.68	10	5.43	10	7.52
	heroin & cocaine	6	3.19	4	2.94	9	4.89	4	3.01
	heroin & meth					2	1.09	1	0.75
	heroin	28	14.89	24	17.65	39	21.20	24	18.05
	other opiates	3	1.60	3	2.21	2	1.09	2	1.50
	methamphetamine	16	8.51	13	9.56	13	7.07	11	8.27
	librium					2	1.09	1	0.75
Stress Because of Alc/Drug Use Past 30 Days	not at all	38	20.32	30	21.90	23	12.50	23	17.29
	somewhat	32	17.11	27	19.71	31	16.85	26	19.55
	considerably	42	22.46	28	20.44	50	27.17	30	22.56
	extremely	75	40.11	52	37.96	79	42.93	53	39.85
	not applicable					1	0.54	1	0.75
Gave Up Activities Because of Alc/Drug Use Past 30 Days	not at all	42	22.46	34	24.82	32	17.39	30	22.56
	somewhat	26	13.90	22	16.06	34	18.48	27	20.30
	considerably	50	26.74	35	25.55	44	23.91	28	21.05
	extremely	68	36.36	45	32.85	73	39.67	47	35.34
	not applicable	1	0.53	1	0.73	1	0.54	1	0.75
Emotional Problems Because of	not at all	56	29.95	46	33.58	51	27.87	47	35.61

Alc/Drug Use Past 30 Days	somewhat	36	19.25	29	21.17	36	19.67	30	22.73
	considerably	38	20.32	26	18.98	38	20.77	20	15.15
	extremely	57	30.48	36	26.28	57	31.15	34	25.76
	not applicable					1	0.55	1	0.76
Importance of Subs Abuse TX After Release	not at all	24	12.70	19	13.77	17	9.34	16	12.21
	somewhat	31	16.40	25	18.12	20	10.99	12	9.16
	considerably	53	28.04	37	26.81	39	21.43	27	20.61
	extremely	81	42.86	57	41.30	106	58.24	76	58.02
Person Responsible for Current TX	judge	36	18.95	28	20.29	27	14.67	19	14.29
	court officer	5	2.63	5	3.62	7	3.80	7	5.26
	substance abuse referral unit	2	1.05	2	1.45				
	correctional classification	7	3.68	6	4.35	7	3.80	7	5.26
	myself	109	57.37	68	49.28	126	68.48	85	63.91
	other criminal justice officer	17	8.95	16	11.59	12	6.52	10	7.52
	other	14	7.37	13	9.42	5	2.72	5	3.76
Ever Gone to Self Help Meetings	No	18	9.52	18	13.14	23	12.57	19	14.39
	Yes	171	90.48	119	86.86	160	87.43	113	85.61
Have Medical Insurance	No	137	72.11	96	69.57	132	71.74	89	66.92
	Yes	53	27.89	42	30.43	52	28.26	44	33.08

Table 6b
Summary of SA History - Baseline
Subjects Randomized and Completing Initial Session (i.e. Parole Initiation Session) through November 30, 2006

		Control (Randomized)	Control (Parole Initiation)	Intervention (Randomized)	Intervention (Parole Initiation)
Days Drank Alcohol Past 30 Days	Valid N	190	138	184	133
	Mean	12.26316	11.37681	11.32065	11.09774
	Median	5	4.5	5	4
	Minimum	0	0	0	0
	Maximum	30	30	30	30
	Std Deviation	12.99793	12.88648	12.34169	12.11239
	25th Percentile	0	0	0	0
	75th Percentile	30	30	25	20
# Drug Overdoses Lifetime	Valid N	190	138	183	132
	Mean	0.542105	0.528986	0.622951	0.727273
	Median	0	0	0	0
	Minimum	0	0	0	0
	Maximum	20	12	25	25
	Std Deviation	2.00418	1.621894	2.340498	2.67328
	25th Percentile	0	0	0	0
	75th Percentile	0	0	0	0
# Times Quit Alc/Drugs for >=3 Mos	Valid N	190	138	183	132
	Mean	5.494737	5.188406	5.497268	5.628788
	Median	4	3.5	4	4
	Minimum	0	0	0	0
	Maximum	40	30	50	50
	Std Deviation	5.648193	5.461946	5.940987	6.652102
	25th Percentile	2	2	2	2
	75th Percentile	7.25	6	7	7

# Times in Substance Abuse TX program	Valid N	188	136	184	133
	Mean	2.345745	2.316176	2.217391	2.082707
	Median	2	2	2	2
	Minimum	0	0	0	0
	Maximum	14	14	11	10
	Std Deviation	2.527418	2.549371	2.216807	2.202083
	25th Percentile	1	1	1	0.5
	75th Percentile	3	3	3	3

Tables 7a and 7b present effect sizes for intervention versus control at randomization and at Parole Initiation Session. There are small effects that suggest that dropout before Parole Initiation within the intervention group may be associated with that group's greater time in jail lifetime and lifetime arrests. This effect might introduce conservative bias making it more difficult to show benefits of the intervention.

Table 7a: Baseline Effect Sizes – Randomized Population

Variable	Cohen's d	Hedges g
Lifetime arrests	.014	.014
Time in jail lifetime (months)	.146	.146
Months in jail lifetime	.086	.086
# of arrests last 6 months	.200	.200
Days in jail last 6 months	.021	.021
Days in jail last 30 days	.133	.133

Table 7b: Baseline Effect Sizes – Parole Initiation Population

Variable	Cohen's d	Hedges g
Lifetime arrests	.233	.233
Time in jail lifetime (months)	.234	.233
Months in jail lifetime	.103	.103
# of arrests last 6 months	.108	.108
Days in jail last 6 months	.149	.149
Days in jail last 30 days	.177	.177

Adherence and Fidelity In the Intervention Group

The proportion attending at least 3 sessions remains excellent at 93.8% (Table 8a), and approximately 80% of sessions have met the strict criteria for fidelity (Table 8b). Because the Induction Session is the key component of the intervention, the time to this session is being monitored as a benchmark that the Induction Session takes place within 2 weeks of the Parole Initiation session. Through the end of November 2006, the average time from Parole Initiation to the Induction Session for all sites was 20.6 days, within individual sites ranging from an average of 12.5 days to 36.2 days. Sites whose average is above 14 days are in the process of developing written plans on how they will work with their correctional partners to reduce the time to the Induction Session.

Table 8a. Attendance at Step'n Out Intervention Sessions by Site As of November 30, 2006

	Mean Number of Sessions Attended (SD)	Mean Number of Points Earned (SD)	% Attending at Least 3 Sessions
RI	4.33 (4.1)	53 (76.7)	1/2 50%
DE	8.83 (3.7)	115.3 (88.2)	21/22* 95.5%
Bridgeport, CT	11.27 (4.9)	134.7 (94.4)	11/11 100%
Hartford, CT	—	—	—
VA	9.31 (4.1)	93.75 (72.4)	14/15 93.3%
OR	8.18 (4.1)	73.3 (71.3)	13/14 92.9%
TOTAL	8.97 (4.3)	100.6 (82.5)	60/64 93.8%

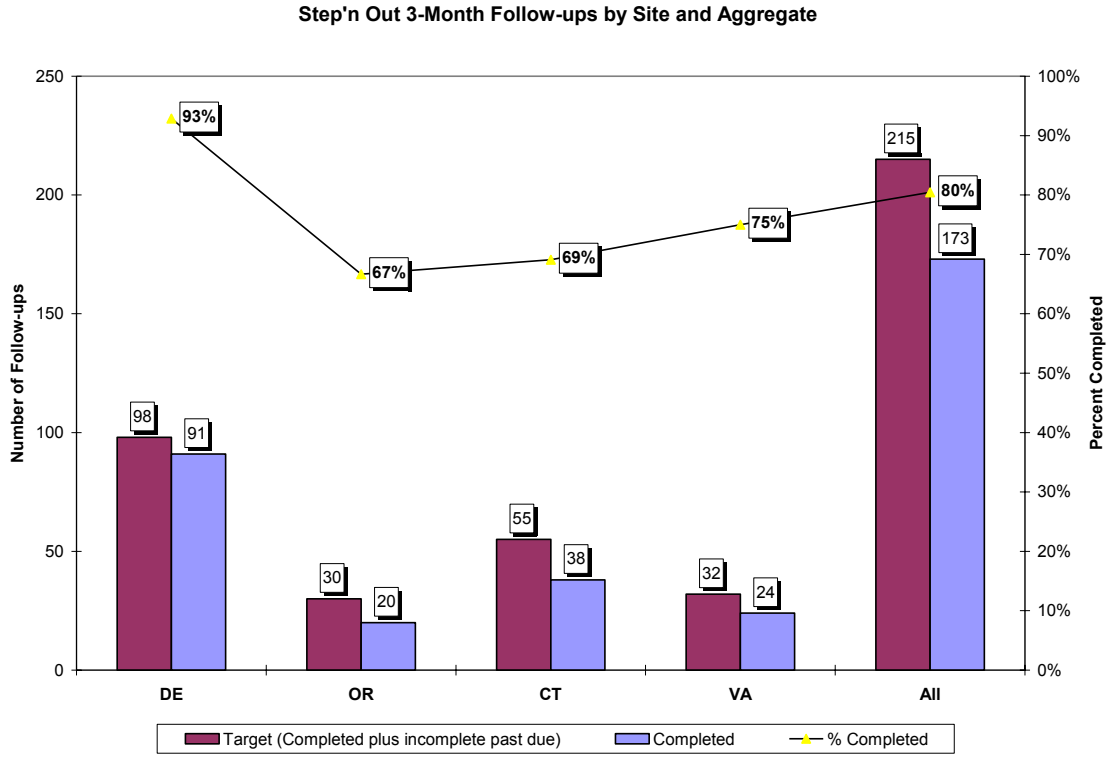
Table 8b. Fidelity during Induction and Subsequent Sessions In Intervention Group

		Overall Fidelity			
		Adherent		Non-adherent	
		Count	%	Count	%
Total Induction Sessions Coded		*45*	*83.3%*	*9*	*16.7%*
Site	Virginia	*5*	*83.3%*	*1*	*16.7%*
	Bridgeport, Connecticut	*6*	*66.7%*	*3*	*33.3%*
	University of Delaware	*22*	*81.5%*	*5*	*18.5%*
	Oregon	*11*	*100.0%*	*0*	*.0%*
	Rhode Island	*1*	*100.0%*	*0*	*.0%*
Total One Month Sessions Coded		*20*	*76.9%*	*6*	*23.1%*
Site	Virginia	*3*	*50.0%*	*3*	*50.0%*
	Bridgeport, Connecticut	*3*	*75.0%*	*1*	*25.0%*
	University of Delaware	*10*	*83.3%*	*2*	*16.7%*
	Oregon	*4*	*100.0%*	*0*	*.0%*

Follow Up Rates

Updated 3 and 9 month follow up rates are given in Figure 1. The diligence of the SNO sites over the past quarter has increased the overall 3-month follow up rate from 59% in June 2006 to 80% at the end of November 2006, and the 9-month rate from 74% to 92%. Table 9 demonstrates that recent changes in definitions of the Initial Session has caused a decrement in 3-month follow-up rates in the intervention group; the SNO research team is aware and is working to follow-up these newly re-added cases. This change has not differentially affected 9-month rates.

Figure 1: 3- and 9-Month Follow Up Rates As Of November 30, 2006



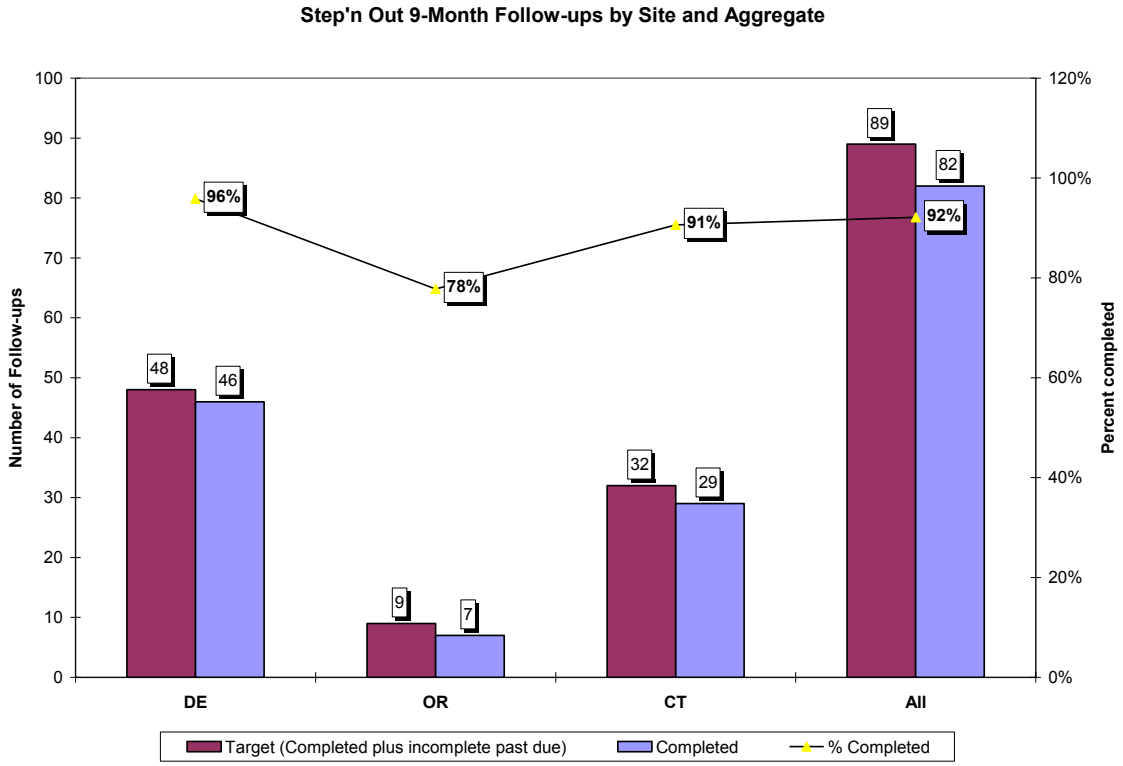


Table 9. Three-Month Follow-up Rates by Study Condition and Site.

Study Condition	Research Center	3 Month Due	3 Month Completed	Percent Complete
Control	Virginia	19	12	63.2%
	Connecticut	30	28	93.3%
	University of Delaware	52	50	96.2%
	Oregon	17	12	70.6%
	Rhode Island	0	0	NA
	Total	**118**	**107**	**90.7%**
Treatment	Virginia	14	12	85.7%
	Connecticut	27	16	59.3%
	University of Delaware	53	43	81.1%
	Oregon	13	7	53.8%
	Rhode Island	0	0	NA
	Total	**107**	**78**	**72.9%**
Total	Virginia	33	24	72.7%
	Connecticut	57	44	77.2%
	University of Delaware	105	93	88.6%
	Oregon	30	19	63.3%
	Rhode Island	0	0	NA
	Total	**225**	**180**	**80%**

Interim Analyses

According to the Step 'N Out Data Safety Monitoring Plan (revised 10/17/2006, posted on the CJ-DATS website), interim analysis was scheduled when 50% of the 3-month follow up data had been collected. For the November 2006 DSMB meeting, partial 3-month data was available on 112 subjects, with substance use outcome data available on 92 cases, because 20 cases only had timeline follow back data that had not yet been aggregated by the data center. Some outliers also require verification.

For the current report, data quality problems have been largely addressed and Interim Analyses are presented for the 180 subjects (36% of 496) with 3-month data as of November 30th. The original plan for the interim analysis was that recidivism would be assessed from administrative data of our correctional partners. All centers have requested criminal justice records from their jurisdictions and all have secured agreements to get these data in time for the originally proposed 50% interim analysis in the first quarter of 2007. All of our partners have obtained such administrative data for past observational studies and we remain confident that these data will be available. However, for this early report requested by the DSMB, only self-reported data are available. Table 10 clarifies interim analysis variable definitions from the DSM Plan:

Table 10: Interim Analysis Variables from DSM Plan

Primary Aims: The Step'n Out intervention will:	**Hypotheses**	**Assessment Point**	**Variable Definition**	**Source of Data**
H1. Reduce recidivism.	Participants in the Step'n Out intervention group will report lower recidivism than will those in the regular parole comparison group.	3 and 9 months following release	*Recidivism*: Number of arrests or technical violations since release – both from official records and from self-report	Official records and self-report at 3-month follow-up
H2. Reduce Crime	Participants in the Step'n Out intervention group will report having committed a fewer number of crimes since release than will those in the regular parole comparison group	3 and 9 months following release	*Crime*: Number of reported crimes in the past 30 days –from self-report	Self-report at 3-month follow-up
H3. Reduce relapse to drug use.	A smaller percentage of participants in the Step'n Out intervention group than in the regular parole comparison group will have used illicit drugs.	3 and 9 months following release	*Drugs*: Use of drugs/ alcohol since release. Self–report includes use and degree of use. Urine screens will be any positive as well as proportion tests failed or missed.	Self-report at 3-month follow-up Follow-up. Positive Urine drug Test or refused tests

Table 11 presents the way in which each outcome variable was operationalized from the existing 3-month follow-up data. The days at risk for the follow-up period were calculated from the Timeline Follow Back (TLFB) form, which captures self-reported arrests, crime, drug use, and location for the subject for each day of the time period. If the client was incarcerated on a given day, they were counted as not at risk on that day for arrest, committing a crime or substance use. This assumption was made for the purposes of interim analysis. Clearly there are issues of informative censoring (i.e. persons incarcerated likely would have committed more crimes or used more drugs had they remained in the community) that will need to be addressed in the final analysis.

Table 11: Interim Variable Definitions

Outcome	**Variable**	**Creation**
Recidivism	Number of arrests or technical violations during the 3 months since the Initial Session / days at risk during the 3 months since the Initial Session	Sum of total arrests on Timeline Follow Back for 3 months since Initial Session (if variable was missing, it was taken from the CJDATS follow up, variable name ARSTFLW)
Reduce Crime	Number of crimes committed last 30 days /days at risk in the last 30 days	Sum of crimes committed on Timeline Follow Back (excluding drug use and/or possession) for 30 days prior to the end of the 3 month period

Reduce relapse to drug use	Number of days of illicit drug use during the 3 months since Initial Session/ days at risk during the 3 months since the Initial Session	Sum days used any drug or alcohol (exclude tobacco from drug list) from Timeline Follow Back for 3 months since Initial Session. Also included positive urine drug tests and drug tests that were refused – these were counted as 3 days of illicit drug use

The TLFB data were used for the interim analysis as this type of structured interview has been found to be the most reliable and valid method of assessing prior substance use. Also, for subjects who missed their 3-month follow up but completed a 9-month interview, the TLFB was completed for the entire period since the Initial Session, so these data are not missing. A total of 43 subjects had TLFB data collected for the entire recall period at their 9-month interview.

For the number of arrests per 100 days at risk in the follow up period, data were taken from two sources. The primary source was the number of arrests reported on the TLFB. If these were missing or were less than the number of arrests reported on the CJ-DATS follow-up form, the number of arrests on the follow-up form was used. A total of 18 records had arrest data from the CJ-DATS follow-up form that were used for this analysis. Ultimately, administrative data will be used to validate these reports. For the crime data, we excluded reports of drug possession because of their overlap with the drug use outcome. To demonstrate how the urine drug screens would be used, urine drug tests that were positive or refused were counted as 3 days of illicit drug use if drug use was not reported on the TLFB calendar.

The TLFB data are reasonably clean for the purposes of this Interim Analysis, but sites are still responding to quality assurance reports on data issues. Tables 12 and 13 present the results of the key variables from 180 cases of 3-month TLFB data, with 78 cases from the intervention group and 102 from the control.

Table 12
3 month Timeline Follow Back: Arrests, Crime and Drug Outcomes

	Intervention			Control		
	Mean	**SD**	**Valid N**	**Mean**	**SD**	**Valid N**
Total arrests/100 days at risk	.27	.67	77	.58	1.96	101
Total crimes (excluding drug use/possession)/days at risk last 30 days	.088	.485	76	.078	.386	98
Percent of days at risk used drugs (including alcohol)	.093	.240	77	.121	.250	101

Point estimates of effects on arrests per days at risk and drug use on risk-days go in the hypothesized directions, but only the estimated effect on arrests reaches Cohen's rule-of-thumb for a small effect size (Table 13). The effect on crime per risk-days is centered on the null.

Table 13: 3-Month Effect Sizes

Variable	Cohen's d	95% CI
Total arrests/days at risk in 3 month follow up period	0.210	-0.087 to 0.507
Total crimes/days at risk last 30 days of 3 month follow up period	-0.023	-0.277 to 0.321
Days used drugs/days at risk in 3 month follow up period	0.115	-0.181 to 0.412

Overall drug use, crime, and arrests for the recall period by study condition are given in Table 14. A smaller percentage of the intervention group (27%) than the control group (35%) used drugs or alcohol at all. Point estimates of effects on overall arrests, crime and drug use are in the hypothesized direction, but below Cohen's threshold.

Table 14 – 3 month Overall Outcomes

Outcome	Intervention	Control	Cohen's d
Any Arrest	18.2%	19.8%	.03
Any Self-Reported Crime last 30 days (except drug use/possess.)	10.4%	11.9%	.03
Any Drug or Alcohol Use	27.3%	34.7%	.17

The urine toxicology data were compared with the self-report of drug use and these results are shown in Table 15. Fewer intervention subjects had positive urine toxicology for drugs than the controls. The control group was less likely to self-report drug use when they had a positive urine toxicology.

Table 15: Urine Toxicology and Self-Report of Drug Use

Study Condition	Total Urines Collected	(+) Urine Toxicology	(+) Urine Toxicology. Without Self-Reported Drug Use
Control	55	17 (31%)	9 (53%)
Intervention	44	10 (23%)	4 (40%)
Overall	91	27 (30%)	13 (48%)

Power Calculation

The DSMB requested a recalculation of power based on effect sizes suggested by the interim analysis. Such effect sizes are point estimates at 3 months based on only the first 36% of projected cases; the confidence intervals around these point estimates are large (see Table 13 above). In order to use information from the interim analysis to project power, it is necessary to consider the following:

(a) The interim analysis uses only about one-third of the projected sample size; hence *estimated effects based on this sample cannot be regarded as accurate estimates of the true effect.* The confidence interval properly reflects the degree of uncertainty. As seen in Table 13, there is considerable uncertainty associated with each estimate of effect. The uncertainty is due primarily to small sample size.

(b) Because of the large degree of uncertainty, it is not appropriate to use the interim point estimates as representations of the underlying true effect size for the purpose of updating power calculations. More appropriate uses of the interim information are:

a. Compute power under a range of effect sizes that are consistent with the interim data; i.e., that fall within the confidence interval.
b. Compare the original hypothesized effect sizes against the current confidence intervals to ensure the interim data are not inconsistent with original hypotheses.

(c) It is of course not possible to guarantee that a particular effect will be statistically significant, because (by definition) 80% power means that a true effect will turn up a significant finding only 80% of the time.

For the primary outcome of arrests per risk-days, the current estimated difference in means is -.31 arrests per 100 risk-days with 95% confidence interval ranging from -.77 to .15 (P=0.19). If we assume the point estimate is exactly equal to the true difference in means, power with N=496 is 65%. As outlined above, this assumption is not entirely appropriate, and information supplied by the confidence interval should be taken into account; the confidence interval is consistent with a true difference in means ranging as large as -0.77 arrests per 100 risk-days, in which case power would exceed 99%. Power will be 80% if the true difference in means is -0.37 arrests per 100 risk-days, an entirely realistic scenario that falls well within the 95% confidence interval from this interim analysis.

For the outcome of days of drug use per days at risk, the current estimated difference in means is -0.03 per risk-day, 95% confidence interval from -.10 to 0.043 (P=.42). If we assume the point estimate is exactly equal to the true difference in means, power with N=422 (assuming a rate of 85% follow-up at 9-months is maintained) is 24%. As outlined above, this assumption is not entirely appropriate, and information supplied by the confidence interval should be taken into account; the confidence interval is also consistent with a true difference in means ranging as large as -.10 days of drug use per risk-day, in which case power would approach 99%. Power will be 80% if the true difference in means is -.067 days of drug use per risk-day, a potentiality that falls well within the confidence interval from this interim analysis.

If current point estimates of effect size remain stable, it appears less likely this study would detect effects on crime as currently defined. For the outcome of crimes per days at risk last 30 days, the current estimated difference in means is .01 additional crimes per risk-day for the intervention group with 95% confidence interval from -.12 to .14 (P=.88). If we assume the point estimate is exactly equal to the true effect size, power with N=422 (assuming a rate of 85% follow-up at 9-months is maintained) is 6%. Power will be 80% if the true difference in means is -.12 crimes per risk-day, a scenario that just falls within the CI from this interim analysis.

Administrative Barriers

One concern in reviewing the Parole Initiation Session data is whether more intervention subjects are dropped before the Parole Initiation Session than control subjects. To determine whether intervention parole officers may be doing more thorough file reviews of the intervention clients than the control parole officers, the Virginia site will conduct file reviews of all control subject files in early January to assess if patterns of Pre-IS dropout appear similar for controls and intervention subjects. A report on this file review will be available in February 2007.

All sites have begun gathering data on the number and dates of parole sessions attended by the control group in order to align with the session attendance data for the intervention group gathered in the SNOCONE program. Quarterly file reviews are planned to extract data on no-show rates to parole and intervention sessions. These data will allow assessment of parole compliance rates for both study conditions. Addiction treatment utilization data will be taken from the 3-month interview.

Summary

The following steps have been taken to address concerns:

- *Number of subjects dropped before the Initial Session* – modified procedures have minimized this possibility. Since 7/2006, only 2 subjects have been dropped before the Initial Session.
- *Imbalance in numbers reaching Initial Session by study condition* – movement of the Initial Session date for the Intervention Condition to the "Parole Initiation" date has resulted in equivalent rates of study entry for the control and intervention groups. Currently, 143 controls and 141 intervention subjects have had their Parole Initiation sessions.
- *Recruitment rates* – Up to November 30, 2006 a total of 284 subjects has reached the Parole Initiation Session, an increase of 36% since August 31, 2006.
- *Follow-up rates* – all sites have made efforts to increase tracking and locating and have increased follow up rates to 80% and 92% for the 3- and 9-month follow up periods. The change to Parole Initiation Session has created a recent decrement in follow-up for the intervention condition that will need to be corrected with follow-up of those cases.
- *Outliers in data* – the Coordinating Center has been sending out monthly reports with out-of-range values to all sites asking for clarification. These outliers are considered missing data until confirmed by sites.
- *Adherence and outcomes* - Criminal justice and file review data will be available in early 2007 to examine outcomes and procedural barriers.

Findings of Interim Analyses include:

- Most baseline characteristics are balanced at randomization and Parole Initiation Session. Two variables (lifetime arrests and lifetime months in jail), if maintained with further recruitment, suggest that the intervention group may have greater lifetime contact with the criminal justice system.
- Analyses of the 3-month data to November 30th suggest:
  - The intervention might exert a small effect (Cohen's d= .211) to reduce arrests per risk-day. Effects on drug use per risk-day also appear to go in the hypothesized direction, but are modest at present.
  - Overall a smaller percentage of the intervention group (27%) than the control group (35%) used drugs or alcohol at all. Overall arrest and crime effects appear to go in the same hypothesized direction, but are trivial.
  - Fewer intervention subjects had positive urine tests for drugs than the controls. Controls appear to be less forthcoming in their self-reported drug use.
- Power analyses suggest that the current difference in means of .31 arrests per 100 risk-days yields power of .65 with total N of 496, but power would rise to .80 if the difference in means rises just .06 arrests per 100 risk-days, a possibility well within current confidence limits.
- There is no evidence that the intervention is causing harm to participants. The original safety concern that more intensive parole supervision in the intervention group might lead to more revocations is not supported. This finding is very important for the field.

Conclusion

Hearkening back to the algorithm described in the Steering Committee letter of December 12th, after the recent changes and improvements in study implementation, *interim analyses and case flow do not suggest that:*

1. *Dropout before the Initial Session was not-at-random.* Most parameters are balanced at randomization and at the Parole Initiation Session. The single domain (lifetime contact with the criminal justice system) that is currently imbalanced at the Parole Initiation Session favors the control group. This effect would likely make any results more conservative.
2. *None of the primary outcomes has any potential to produce an effect size that will be small or larger.* The intervention has potential to exert a small or larger effect (Cohen's d= .211; 95% CI, -0.087 to 0.508) on the primary outcome of arrests per risk day. The confidence intervals for the three primary outcomes include the potential for detectable effects. These very preliminary estimates do not adjust for the baseline finding that the intervention group might have had a more severe incarceration history than the control group, and do not account for the possibility suggested by the urine toxicology findings that control subjects may be less forthcoming in their self-reports. They also do not account for differences in self-report follow-up rates between the study conditions and the likelihood that recent inclusion of intervention subjects who completed the Parole Initiation Session but not Induction or Subsequent Sessions will decrease the effect size. Future interim analyses including the use of criminal justice administrative data should examine these issues.
3. *Recruitment will be insufficient to provide power to detect a small or larger effect for any of the primary outcomes at conventional levels.* Recruitment should be sufficient to provide power to detect a difference in mean arrests of .37 per 100 risk-days. This effect size is well within the 95% CI based on the Interim Analysis.

Based on these data and analyses, it seems reasonable to urge the continuation of the Step'n Out study. It seems appropriate to arrange a conference call between the Steering Committee, NIDA and the DSMB to discuss issues to be considered in the further conduct of this study as well as an appropriate monitoring strategy.