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CHAPTER 21

CLINICAL MONITORING PROCEDURES

21.1 INTRODUCTION

DISC will monitor study participants and their parents for the identification of possible medical problems requiring further investigation and possible referral. Clinical monitoring procedures are for screening purposes only, and are not intended to be diagnostic. If a referral is made, the definitive assessment of the participant's or parent's medical status will be carried out by his or her physician who will also be responsible for treatment.

The purposes of clinical monitoring in DISC are:

1. To detect possible cases of inadequate growth or nutrition, delayed sexual maturation, blood chemistry abnormalities, or psychosocial abnormalities in the DISC study sample.
2. To keep records of study participants identified as having potential problems and to track their DISC clinic review, referral and follow-up.

Clinical monitoring will be the joint responsibility of clinical centers and the Coordinating Center with clinical centers having faster access to data on Tanner, menstrual bleeding, blood pressure and psychosocial tests, and the Coordinating Center having faster access to lipid, blood chemistry, changes in height and weight, and NCC results as well as the ability to compile complete lists of abnormal clinical monitoring values for all clinics. For those data available, the process of detecting and reviewing results over or under specified clinical monitoring cutpoints should begin at clinical centers as soon as possible after measurements are made.

For a more detailed explanation of clinical cutpoints and requirements for DISC clinical monitoring, please refer to Chapter 9 of the DISC Protocol.

21.2 CLINICAL MONITORING INDICATORS

The following clinical indicators will be monitored in DISC participants:

1. For inadequate growth: weight, height velocity.
2. For anemia: hemoglobin, serum ferritin.
3. For delayed sexual maturation: Tanner staging of breast and genital development, and age at menarche.
4. For excessive menstrual bleeding in girls at menarche: bleeding for more than 10 consecutive days.
5. For hypertension (in both participants and parents): blood pressure.
6. For blood lipid abnormalities (in both participants and parents): lipid profile.
7. For blood chemistry abnormalities: selected results from the chemistry panel.
8. For psychosocial abnormalities: psychosocial developmental scores, eating disorders and reports of intended or attempted suicide.

A detailed table summarizing monitoring cutpoints for each measure available at the time of the exam is presented in Appendix A. A complete table of monitoring cutpoints is presented in Appendix B and in the DISC Protocol Chapter 9.

The listed indicators are measured at the following visits:

	VISIT											
INDICATOR	BL	06	12	24	36	48	YR5	YR6	YR7	YR8	YR9	Final
Height	X	X	X	X	X	X	X	X	X	X	X	X
Weight	X	X	X	X	X	X	X	X	X	X	X	X
Hemoglobin	X		X		X							X
Ferritin	X		X		X							X
Tanner Stage	X	X	X	X	X	X	X	X	X	X	X	X
Menstrual History					X		X		X		X	X
Blood Pressure	X		X		X							X
Blood Lipids	X		X		X		X		X		X	X
Blood Chemistry	X		X		X							
Psychosocial tests	X		X		X							X

All DISC centers will use the most recently collected data for clinical monitoring purposes.

21.3 MONITORING REPORTING PROCEDURES

21.3.1 Clinical Center Procedures

Clinical Centers will detect abnormal results in two ways: as measurements are made for data that is available at the clinic; and by reviewing the "Clinical Monitoring List" that they will receive from the Coordinating Center.

1) Data collectors should review results for clinical monitoring cutpoints at the exam as measurements on parents or children are carried out.

   a. A list of monitoring cutpoints for results available at the time of the exam (Appendix A) should be available at the examination site for easy reference.

b. When a result which exceeds a monitoring cutpoint is encountered during the examination, a Clinical Monitoring Form 69 should be initiated. Part 1 of the Clinical Monitoring Form 69 (see attached) should be completed by the data collector or reviewer who detects the abnormal result(s).

c. One Clinical Monitoring Form per abnormal result should be used.

d. The form should then be given to the clinic physician (medical results) or the clinic psychologist (behavioral results) who will complete the Referral Report. The mode of referral is at the discretion of the DISC physician or psychologist.

2) For all results over or under clinical monitoring cutpoints, an in-clinic review is required:

a. If the psychologist or physician determines that referral is not justified, Form 69 Item 2 should be completed by the clinic physician or psychologist with question 2D answered "No" indicating that a referral to an outside health care provider was not recommended.

b. If the psychologist or physician determines that a referral is justified, the Form 69 Item 2 should be completed with question 2D answered "Yes", and a Referral Report should be completed. The mode of referral will be at the discretion of the clinic physician or psychologist. The Referral Report should be accompanied by an appropriate cover letter.

c. If an extremely high BP, very heavy menstrual bleeding, or a suicide plan is detected during the exam, the response should be investigated by the clinic physician or psychologist immediately, and an extra effort should be made to contact the parent before he/she leaves the clinic. If he/she has already left the clinic, a phone call should be made immediately. Extremely high results should be brought to the attention of the clinic Principal Investigator immediately.

3) When the Clinical Monitoring List is received from the Coordinating Center, previously detected abnormal results should be verified against the list. The list should be further checked for abnormal values that may have been missed or not available at the time of the exam. Clinical monitoring procedures as outlined in #2 above should be started for these abnormal results.

4) After the completion of Form 69 Items 1 - 3 and the attachment of the Referral Report (if any), the psychologist or physician should give the finished form to the clinic Principal Investigator. He/she should review all actions taken and sign in the space provided (Item 4) on the Clinical Monitoring Form. A letter from the health care provider can be used in place of the Referral Report. However, the Referral Report or the letter must be signed by the health care provider. If a letter is used, the name of the child should be blacked out and the ID and namecode affixed.

5) If no response to the Referral Report is received from the health care provider, the parent should be recontacted approximately three months after the initial notification. If the parent chooses not to follow-up, it should be indicated on the Clinical Monitoring Form question #3C and a copy should be sent to the Coordinating Center.

6) Clinical Monitoring Forms with their Referral Reports (if any) attached should be sent to the Coordinating Center and copies should be kept at the clinic.

7) Verification of clinical monitoring abnormal values can be done through retesting at the clinic's discretion. Retesting should be noted in question #2C of the Form 69. A copy of forms or records resulting from retesting should be attached to the Form 69 as documentation of actions taken. Originals should be filed at the clinic with the Form 69.

21.3.2 Coordinating Center Procedures

1) The DISC Coordinating Center will monitor incoming study forms for abnormal results which exceed clinical monitoring cutpoints. If an abnormal result is detected, it will be included in the Clinical Monitoring List and sent to the Clinical Center where the participant was seen.

2) The Clinical Monitoring List will be sent to DISC clinics along with regular edit messages. Abnormal results will be reported by ID, namecode and visit number. All abnormal results for an individual will be listed on a single page.

3) Clinical Monitoring Forms received from clinics will be checked against outstanding Clinical Monitoring Lists.

Delinquent form messages for the Form 69 will be sent to clinics with their regular delinquent forms list.

4) The Coordinating Center will maintain a database for the clinical monitoring of all DISC participants and will generate quarterly reports on the status of clinical monitoring for the DISC Clinical Monitoring Committee. Reports will also be generated for review by the DISC Steering Committee and the Data and Safety Monitoring Committee.

APPENDIX A

LIST OF DISC CLINICAL MONITORING CUTPOINTS FOR RESULTS AVAILABLE AT THE EXAM

1. PUBERTAL STAGES -

Girls:

Stage	Age
Breast II	≥ 13 years
Breast IV	≥ 15.3 years
Pubic hair II	≥ 13.4 years
Pubic hair IV	≥ 15 years
Menarche	≥ 15 years

Boys:

Stage	Age
Testes 4 ml	≥ 13.5 years
Testes 12 ml	≥ 16.5 years
Pubic hair II	≥ 14 years
Pubic hair IV	≥ 16 years

2. HEMOGLOBIN - Less than 11 g/dl or a decrease of 1.5 g/dl between measurements. (See Protocol Section F.2 for additional requirements.)

3. CHILD BLOOD PRESSURE-

Age	Systolic BP	Diastolic BP
6 - 9 years	≥ 122 mm Hg	≥ 76 mm Hg (K4)
10 - 12 years	≥ 126 mm Hg	≥ 82 mm Hg (K4)
13 - 15 years	≥ 136 mm Hg	≥ 86 mm Hg (K5)
16 - 18 years	≥ 142 mm Hg	≥ 92 mm Hg (K5)

4. PSYCHOSOCIAL BATTERY

Depression:
- CDI > 14
- Beck Form > 19

Suicide:
- CDI Ques. 9C = Yes
- Beck Form Ques. 2 = 2 or 3
- Beck Form Ques. 9 = 2 or 3
- Achenbach (CBCL) Ques. 18 = Somewhat or Very True (either parent)
- Achenbach (CBCL) Ques. 91 = Somewhat or Very True (either parent)
- Achenbach (YSR) Ques. 18 = Somewhat or Very True (participant)
- Achenbach (YSR) Ques. 91 = Somewhat or Very True (participant)

Behavior Problems:
- Achenbach (CBCL) Total Behavior Problem Score > 90th %
- Achenbach (YSR) Total Behavior Problem Score > 90th %

LIST OF DISC CLINICAL MONITORING CUTPOINTS FOR RESULTS AVAILABLE AT THE EXAM

4. PSYCHOLOGICAL BATTERY (Continued)

Anxiety:	STAIC Total Trait Anxiety Score > 45 STAIC (Self-Evaluation Form) Total Trait Anxiety Score > 52
Eating Disorders:	
Anorexia -	Worrisome/alert % IBW and any item from screening question = Yes (except Item A)*
Bulimia -	Screening question = Yes (Item E)*
5. PARENT BLOOD PRESSURE-	Systolic BP $\geq$ 140 mm Hg OR Diastolic BP $\geq$ 90 mm Hg

*During the past 30 days, did you do any of the following things to lose weight or to keep from gaining weight?

A. I did not try to lose weight or keep from gaining weight.
B. I dieted.
C. I ate very little for one or more days.
D. I exercised to lose weight or keep from gaining weight.
E. I made myself throw up.
F. I took diet pills.
G. I used laxatives, Ipecac, or diuretics.
H. I used diet drinks such as Slim Fast.
I. I used some other method (specify):

APPENDIX B

SUMMARY TABLE
CLINICAL MONITORING CUTPOINTS

1. Height Velocity*	1 Year	2 Years
Boys (9-13)	< 3 cm	< 8 cm
Girls (8-11)	< 3 cm	< 8 cm

2. % IBW

Worrisome: 85% ≤ % IBW < 90%
and decrease of > 12 percentage pts./12 months or ≥ 8 percentage pts./6 months

Alert: % IBW < 85%

Overweight: % IBW > 130% or
gain of ≥ 12 percentage pts./12 months or
≥ 8 percentage pts./6 months
(Intervention Only)

3. Pubertal Stages

Girls Stage:	Should reach stage by:
Breast II	13 years
Breast IV	15.3 years
Pubic hair II	13.4 years
Pubic hair IV	15 years
Menarche	15 years

Boys Stage:	Should reach stage by:
Testes 4 ml	13.5 years
Testes 12 ml	16.5 years
Pubic hair II	14 years
Pubic hair IV	16 years

4. Menstrual Bleeding > 10 consecutive days

5. Hemoglobin < 11 g/dl or decrease of 1.5 g/dl between last 2 measurements

6. Ferritin < 7 ng/ml

*Not monitored at FV01.

APPENDIX B (Continued)

SUMMARY TABLE
CLINICAL MONITORING CUTPOINTS

7. Blood Chemistry Monitoring Cutpoints

Variable	Lower Limit	Upper Limit
Albumin	3.1	5.8
Total Protein	5.5	8.8
SGPT (ALT)	--	67.5
SGOT (AST)	--	76.3
Glucose	50.0	110.0
Urea Nitrogen	--	25.8
Creatinine	--	1.1
Total Bilirubin	--	1.4
Direct Bilirubin	--	0.5
Calcium	7.4	11.1
Phosphorus	2.4	7.1
Uric Acid	1.1	6.4

8. Blood Lipids

	Referral Cutpoint
LDL-Cholesterol:	> 160 mg/dl
Triglycerides:	> 200 mg/dl

9. Blood Pressure

Classification of Hypertension by Age Group

6 - 9 Years:	Systolic BP => 122 mm Hg Diastolic BP => 76 mm Hg (K4)
10 - 12 Years:	Systolic BP => 126 mm Hg Diastolic BP => 82 mm Hg (K4)
13 - 15 Years:	Systolic BP => 136 mm Hg Diastolic BP => 86 mm Hg (K5)
16 - 18 Years:	Systolic BP => 142 mm Hg Diastolic BP => 92 mm Hg (K5)

APPENDIX B (Continued)

SUMMARY TABLE
CLINICAL MONITORING CUTPOINTS

10. Psychosocial Scales

Depression:	CDI > 14 Beck Form > 19
Suicide:	CDI Ques. 9C = Yes Beck Form Ques. 2 = 2 or 3 Beck Form Ques. 9 = 2 or 3 Achenbach (CBCL) Ques. 18 = Somewhat or Very True (either parent) Achenbach (CBCL) Ques. 91 = Somewhat or Very True (either parent) Achenbach (YSR) Ques. 18 = Somewhat or Very True (participant) Achenbach (YSR) Ques. 91 = Somewhat or Very True (participant)
Behavior Problems:	Achenbach (CBCL) Total Behavior Problem Score > 90th % Achenbach (YSR) Total Behavior Problem Score > 90th %
Anxiety:	STAIC Total Trait Anxiety Score > 45 STAIC (Self-Evaluation Form) Total Trait Anxiety Score > 52
Eating Disorders:	
Anorexia -	Worrisome/alert % IBW and any item from screening question = Yes (except Item A)*
Bulimia -	Screening question = Yes (Item E)*

11. Parent Measurements

Total Cholesterol:	> 240 mg/dl
Systolic BP:	≥ 140 mm Hg
Diastolic BP:	≥ 90 mm Hg

*During the past 30 days, did you do any of the following things to lose weight or to keep from gaining weight?

A. I did not try to lose weight or keep from gaining weight.
B. I dieted.
C. I ate very little for one or more days.
D. I exercised to lose weight or keep from gaining weight.
E. I made myself throw up.
F. I took diet pills.
G. I used laxatives, Ipecac, or diuretics.
H. I used diet drinks such as Slim Fast.
I. I used some other method (specify):

DIETARY INTERVENTION STUDY IN CHILDREN
CLINICAL MONITORING FORM

DISC Form 69
Rev 2 05/09/95

ID ___-___ ___ ___ ___-___
NC ___ ___ ___ ___ ___ ___
VN ___ ___ ___ ___

INSTRUCTIONS: A separate form should be completed for EACH abnormal result. Item 1 should be completed by clinic staff. Items 2-3 should be completed by the clinic physician or psychologist. When the form is completed, the clinic PI should sign Item 4. Attach the Referral Report (if any) and send copies to the Coordinating Center. Please PRINT all responses CLEARLY.

1. A. Today's date: ..... ____ (Month) - ____ (Day) - ____ (Year)

   B. Date of measurement for this result: ..... ____ (Month) - ____ (Day) - ____ (Year)

   C. Reason(s) for initiating Form 69 (Include ALL measures and values):

   _____

   _____

   _____

   D. Form 69 initiated by: .....[Name] _____

2. A. Date of clinical review: ..... ____ (Month) - ____ (Day) - ____ (Year)

   B. Review carried out by: .....[Name] _____

   C. Results of review and SPECIFIC reasons for decision:

   _____

   _____

   _____

   D. Was an out-of-clinic referral recommended? ..... ( )1 Yes ( )2 No

   If NO, skip to Item 4.

3. A. Date Referral Report given to parent: ..... ____ (Month) - ____ (Day) - ____ (Year)

   B. Date Referral Report given to health care provider: ..... ____ (Month) - ____ (Day) - ____ (Year)

   C. Was a response to referral received? ..... ( )1 Yes ( )2 No

   D. Is a completed Referral Report attached? ..... ( )1 Yes ( )2 No

4. _____ PI Signature Date: ____ (Month) - ____ (Day) - ____ (Year)

DISC CC use: Number of forms: _____

DIETARY INTERVENTION STUDY IN CHILDREN
REFERRAL REPORT

DISC Form 69
Rev 2 05/02/95

ID ___-___ ___ ___ ___-___
NC ___ ___ ___ ___ ___ ___
VN ___ ___ ___ ___

PART I

ABNORMAL TEST RESULT(S) AND DATE OF DISC CLINICAL MEASUREMENT:

Date: _____ Test: _____ Result: _____

Date: _____ Test: _____ Result: _____

Date: _____ Test: _____ Result: _____

Date: _____ Symptom: _____

PART II

RESULTS OF THE HEALTH CARE PROVIDER'S ASSESSMENT OF PATIENT'S MEDICAL STATUS:

A. Test(s) performed:

Date: _____ Test: _____ Result: _____

Date: _____ Test: _____ Result: _____

Date: _____ Test: _____ Result: _____

B. Diagnosis: _____

C. Follow-up Treatment Plan: _____

_____

_____

D. Comments: _____

_____

_____

Date: _____

Signature of health care provider: _____

DIETARY INTERVENTION STUDY IN CHILDREN
CLINICAL MONITORING FORM

DISC Form 69
Rev 2 05/02/95

ID ___-___ ___ ___ ___ ___-___
NC ___ ___ ___ ___ ___ ___
VN ___ ___ ___ ___

INSTRUCTIONS: A separate form should be completed for EACH abnormal result. Item 1 should be completed by clinic staff. Items 2-3 should be completed by the clinic physician or psychologist. When the form is completed, the clinic PI should sign Part 4. Attach the Referral Report (if any) and send copies to the Coordinating Center. Please PRINT all responses CLEARLY.

1. A. Today's date: ..... ___ ___ - ___ ___ - ___ ___
Month Day Year

B. Date of measurement for this result: ..... ___ ___ - ___ ___ - ___ ___
Month Day Year

C. Reason(s) for initiating Form 69 (Include ALL measures and values):

_____

_____

_____

D. Form 69 initiated by: .....[Name] _____

2. A. Date of clinical review: ..... ___ ___ - ___ ___ - ___ ___
Month Day Year

B. Review carried out by: .....[Name] _____

C. Results of review and SPECIFIC reasons for decision:

_____

_____

_____

D. Was an out-of-clinic referral recommended? ..... ( )1 Yes ( )2 No

If NO, skip to Item 4.

3. A. Date Referral Report given to parent: ..... ___ ___ - ___ ___ - ___ ___
Month Day Year

B. Date Referral Report given to health care provider: ..... ___ ___ - ___ ___ - ___ ___
Month Day Year

C. Was a response to referral received? ..... ( )1 Yes ( )2 No

D. Is a completed Referral Report attached? ..... ( )1 Yes ( )2 No

4. _____ Date: ___ ___ - ___ ___ - ___ ___
PI Signature Month Day Year

DISC CC use: Number of forms: _____

DIETARY INTERVENTION STUDY IN CHILDREN
REFERRAL REPORT

DISC Form 69
Rev 2 05/02/95

ID ___-___ ___ ___ ___-___
NC ___ ___ ___ ___ ___ ___
VN ___ ___ ___ ___

PART I

ABNORMAL TEST RESULT(S) AND DATE OF DISC CLINICAL MEASUREMENT:

Date: _____ Test: _____ Result: _____

Date: _____ Test: _____ Result: _____

Date: _____ Test: _____ Result: _____

Date: _____ Symptom: _____

PART II

RESULTS OF THE HEALTH CARE PROVIDER'S ASSESSMENT OF PATIENT'S MEDICAL STATUS:

A. Test(s) performed:

Date: _____ Test: _____ Result: _____

Date: _____ Test: _____ Result: _____

Date: _____ Test: _____ Result: _____

B. Diagnosis: _____

C. Follow-up Treatment Plan: _____

_____

_____

D. Comments: _____

_____

_____

Date: _____

Signature of health care provider: _____

DIETARY INTERVENTION STUDY IN CHILDREN (DISC)

SAMPLE LETTER FOR CLINICAL MONITORING REFERRAL
FOR NEW MEASUREMENTS (DURING THE LAST YEAR)

[DISC Clinical Center Letterhead] Date

Inside address to Health Care Provider

Dear [Health Care Provider],

Your patient [Participant's Name], is a participant in the Dietary Intervention Study in Children (DISC) and has been identified as having an abnormal measurement. At our routine visit(s) your patient had the test result(s) or symptom in the last 12 months as indicated on the attached Referral Report (Part 1).

Upon your assessment of the medical status of this patient and your decision on a course of therapy (if necessary), please notify us of the outcome by returning the Referral Report in the envelope provided with the information in Part 2 completed.

For further information on the Dietary Intervention Study in Children or on this patient, I may be reached at [PI Telephone Number].

Your cooperation in this matter is appreciated.

Sincerely,

Principal Investigator
[Name of DISC Clinic]

DIETARY INTERVENTION STUDY IN CHILDREN (DISC)

SAMPLE LETTER FOR CLINICAL MONITORING REFERRAL
FOR NEW MEASUREMENTS (DURING THE LAST YEAR)

[DISC Clinical Center Letterhead] Date

Inside address to Health Care Provider

Dear [Health Care Provider],

Your patient [Participant's Name], is a participant in the Dietary Intervention Study in Children (DISC) and has been identified as having an abnormal measurement. At our routine visit(s) your patient had the test result(s) or symptom in the last 12 months as indicated on the attached Referral Report (Part 1).

Upon your assessment of the medical status of this patient and your decision on a course of therapy (if necessary), please notify us of the outcome by returning the Referral Report in the envelope provided with the information in Part 2 completed.

For further information on the Dietary Intervention Study in Children or on this patient, I may be reached at [PI Telephone Number].

Your cooperation in this matter is appreciated.

Sincerely,

Principal Investigator
[Name of DISC Clinic]

DIETARY INTERVENTION STUDY IN CHILDREN (DISC)

SAMPLE LETTER FOR CLINICAL MONITORING REFERRAL
FOR OLD MEASUREMENTS (OLDER THAN ONE YEAR)

[DISC Clinical Center Letterhead]

_____

[Inside address to Health Care Provider]

_____

Dear [Health Care Provider],

Your patient ___[Participant's Name]___, is a participant in the Dietary Intervention Study in Children (DISC). A review of our records for visits older than one year has shown that your patient had the test result(s) or symptom on the date indicated on the attached Referral Report (Part 1).

Upon your review of the medical status of this patient and your decision on a course of therapy (if necessary), please notify us of the outcome by returning the Referral Report in the envelope provided with the information in Part 2 completed.

For further information on the Dietary Intervention Study in Children or on this patient, I may be reached at ___[PI Telephone Number]___.

Your cooperation in this matter is appreciated.

Sincerely,

Principal Investigator
[Name of DISC Clinic]

«Date»

Dear Colleague:

«FirstName» «LastName» is a participant in the Dietary Intervention Study in Children (DISC). Because DISC is a research study, very strict "cutpoints" for normal values are established to ensure the safety of participation in the study. At our routine visit «FirstName» was identified as having a measurement that falls outside those specific "cutpoints". According to our protocol, the parent/guardian has been notified and given a Referral Report to be forwarded to their doctor.

«FirstName» «LastName» had the following test result(s) or symptom(s) as indicated on the attached Referral Report (Part 1). Upon your assessment of the status of this patient and your decision on a course of therapy, if necessary, please notify us of the outcome by completing Part 2 of the Referral Report and returning it in the envelope provided.

For further information about the Dietary Intervention Study in Children or about this patient, I may be reached at 319-356-2839.

Sincerely,

Ronald M. Lauer, M.D.
Principal Investigator

Lynette Stickney
Clinic Coordinator

«Date»

«Mother» and «Father» «Parent_Lastname»
«Address1»
«City», «State» «PostalCode»

Dear «Mother» and «Father»,

Let me first thank you for allowing your child, «FirstName», to participate in the DISC study; «he_she» is very important to us. Recently, «he_she» was seen by our DISC examiner. It has come to our attention that a laboratory value or a particular finding on «his_her» physical examination does not fall into specific guidelines established by DISC. Because DISC is a research study, very strict "cutpoints" for normal values are established to ensure the safety of your child's participation in our study. According to our DISC protocol, if a child falls outside those specific "cutpoints", the parents are to be notified and a Referral Letter sent. Attached is the Referral letter we ask you to give to your doctor. Your doctor, in turn, can evaluate this issue and provide you with a plan of therapy, if he/she feels one is necessary. We will also receive a copy of his/her decision for our files.

Thank you for your cooperation. Do not hesitate to contact me at 319-356-2839 if you have any questions.

Sincerely,

Ronald M. Lauer, M.D.
Principal Investigator

Lynette Stickney
Clinic Coordinator

enclosure

parenref

February 22, 1996

MEMORANDUM

TO: DISC Clinic Coordinators and Intervention Directors*

FROM: Kathleen Brown, DISC Coordinating Center

SUBJECT: Body Mass Index Cutpoints for Clinical Monitoring

The attached page, Table 1, is a draft version of the new body mass index (BMI) cutpoints which will be used in clinical monitoring to screen for abnormal growth and anorexia values. The formula for calculating BMI will be: weight in kg / height in meters, squared. Percent ideal body weight (%IBW) will be the preferred measure when available, but will be replaced by BMI when the child becomes too tall to calculate %IBW. When screening for increases or decreases in BMI, the cutpoints described in parts C. and D. of Table 1 refer to one year changes. The units specified in parts C. and D. are units of BMI, and not percentage points of change.

Now that we have the new BMI cutpoints, the Coordinating Center will be calculating and checking the BMI of participants who were too tall for the calculation of %IBW as far back as the 36 month visit. You may be receiving clinical monitoring notices on these older abnormal growth and anorexia values in the near future. Please handle them in the same way as you have handled other abnormal values more than one year old.

After Table 1 BMI cutpoints have been approved by the DISC Steering Committee, you will receive revised Manual of Operations and Protocol clinical monitoring chapters. We will have an opportunity to discuss the new BMI cutpoints at the April 12 subcommittee meetings in Bethesda.

Please call me at the Coordinating Center if you have questions.

* Janet Freedman/ Martha Cecil
Flora Gosch/ Niki Gernhofer
Lynette Stickney/ Lois Ahrens
Susan Ritter/ Vera Lasser
Patrice Clesi/ Kris von Almen
Shirley Craddick

cc: Bruce Barton
Eva Obarzanek
Denise Simons-Morton

Memo to Frank Franklin
October 10, 1995

TABLE 1. Proposed Cutpoints for Identifying High and Low BMI and High and Low Annual Changes in BMI

A. Alert Levels for Low BMI

Boys:		Girls:	
Age 12	≤15.0	Age 12	≤15.0
Age 13	≤16.0	Age 13	≤15.5
Age 14	≤16.5	Age 14	≤16.0
Age 15	≤17.0	Age 15	≤16.5
Age 16-18	≤18.0	Age 16-18	≤17.5

B. Alert Levels for High BMI (for Intervention Children)

Boys:		Girls:	
Age 12	≥25.0	Age 12	≥26.0
Age 13	≥26.0	Age 13	≥27.0
Age 14	≥27.0	Age 14	≥28.0
Age 15	≥28.0	Age 15	≥29.0
Age 16	≥29.0	Age 16	≥29.0
Age 17	≥29.0	Age 17	≥30.0
Age 18	≥30.0	Age 18	≥30.0

C. Alert Levels for Decreases in BMI

Boys:		Girls:	
Up until age 15	≤-1.0	All ages:	≤-0.75
Age ≥ 16	<-0.75		

D. Alert Levels for Large Increases in BMI (for Intervention Children)

Boys:		Girls:	
Up until age 15	>3.0	Up until age 14	>3.0
Age ≥ 16	>2.5	Age ≥ 15	>2.5