

**Baby hug Follow-up Study (BHFS)
ENROLLMENT**

Form 001
Revision 2

Tue Sep 22 10:14:39 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

Part II: Enrollment Information

1. Did this child complete at least 18 mos. of randomized treatment in BABY HUG?

TREAT_COMPLET

If No, Skip to Part III.1.

(inel)

2. Has informed consent been obtained?

FOLLOWUP_STUDY

If No, Skip to Part III.1.

3. Consent Information;

A. Consent Date:

CONSENT_DT

B. Consent for data file to include child's information?

DATA_CONSENT

C. Consent for blood and urine specimens to be saved indefinitely?

BLOOD_SAVE_CONSENT

D. Consent for blood and urine specimens to be used for future research on sickle cell disease and related disorders?

BLOOD_FUTURE_CONSENT

4. Follow-up Group

FOLLOWUP_GROUP

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5. End of randomization - Therapy of choice

A. Open Label Hydroxyurea?

HYDROXYUREA

If Yes, Complete Form 2 - Patient Treatment Plan

B. Chronic Transfusion?

CHRONIC_TRANSFUSION

C. Other?

OTHER

1. If yes, specify:

SP

PART III: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

CERT_NO

B. Signature

CERT_SIG

C. General Comments

GEN_CMNT

**Baby hug Follow-up Study (BHFS)
PATIENT TREATMENT PLAN**

Form 002
Revision 2

Tue Sep 22 10:18:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: OPEN LABEL HYDROXYUREA DOSING INFORMATION

1. Date HU Started:
2. Dose Started:
3. Dose Form (choose one):

START_DT
DOSE_WEIGHT
DOSE_FORM

PART III: TREATMENT PLAN

1. A. Is there an ANC below which you will hold open label HU treatment?
 - B. If Yes,
 1. If Other, then specify:

ANC_LOW
TREAT_DOSE1
DOSE_SP1

**Baby hug Follow-up Study (BHFS)
PATIENT TREATMENT PLAN**

Form 002
Revision 2

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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2. A. Is there a platelet count below which your institution will hold open label HU treatment?

B. If Yes,

1. If Other, then specify:

C. Is there a hold that can be started based on spleen size or change in spleen size?

3. A. Is there a hemoglobin below which your institution will hold open label HU treatment:

If No, Skip to Part III.4A.

If Yes, choose all that apply

1. 6 gm/dl or below
2. 5.5 gm/dl or below
3. 5 gm/dl or below
4. Percentage below baseline
 - a. If percentage below baseline, specify percentage
5. Other
 - a. If Other, specify:

PLATELET_LOW
TREAT_DOSE2
DOSE_SP2
SPLEEN_CHANGE
HEMOGLOBIN_LOW

HEMO_6GM_DL
HEMO_5_5GM_DL
HEMO_5GM_DL
PCT_BELOW_BASELINE
BELOW_BASLINE_PERC
HEMO_LOW_OTHER
HEMO_AMOUNT_SP

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PATIENT TREATMENT PLAN

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4. A. Is there a hemoglobin/reticulocyte combination at which your institution will hold open label HU treatment?

HEMO_RETICULO

B. If yes,

1. Hemoglobin of

HEMO_AMOUNT2

2. Absolute Reticulocyte of

RETICULOCYTE_NUM

If you answered No to 1, 2, 3 and 4, Skip to Part IV.

5. If your institution holds HU, when will the patient return for the next blood count (choose one)?

NEXT_COUNT

1. If Other, then specify:

NEXT_COUNT_SP

6. How much HU does your institution prescribe at each blood count check?

MEDICATION

A. If Other, then specify:

MEDICATION_SP

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PATIENT TREATMENT PLAN**

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PART IV: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number:
- B. Signature
- C. General Comments

CERT_NO
CERT_SIG
GEN_CMNT

**Baby hug Follow-up Study (BHFS)
STUDY ENTRY**

Form 003
Revision 1

Tue Sep 22 10:19:03 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: SPECIMEN COLLECTION

1. Urine or Microalbumin: Creatine(5 ml)

A. Label number

URINE_LABEL	URINE_LABEL_ND
--------------------	-----------------------

B. Date collected

URINE_DT

2. Stored Blood sample (5ml EDTA lavender top)

A. Label number

BLOOD_LABEL	BLOOD_LABEL_ND
--------------------	-----------------------

B. Date Collected

BLOOD_DT

3. Cystatin C*

A. Label number

CYSTATIN_C_LABEL	CYSTATIN_C_ND
-------------------------	----------------------

B. Date Collected

CYSTATIN_C_DT

*Cystatin C should only be collected if a specimen was not obtained upon exit of the BABY HUG Treatment Study. Coordinator should contact the MCC to verify whether or not Cystatin C should be collected.

Baby hug Follow-up Study (BHFS)
STUDY ENTRY

Form 003
Revision 1

Tue Sep 22 10:19:03 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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PART III: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number:
- B. Signature
- C. General Comments

CERT_NO
CERT_SIG
GEN_CMNT

**Baby hug Follow-up Study (BHFS)
CLINICAL DATA REPORT**

Form 010
Revision 4

Tue Sep 22 10:20:47 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: INTERVAL INFORMATION

1. Visit
2. Interval Start Date:
3. Interval End Date:
4. Any patient contact during this interval?
 - A. If No, reason:
If No, Skip to Part IX.

VISIT
INTERVAL_START_DT
INTERVAL_END_DT
PATIENT_CONTACT
PATIENT_CONTACT_RSN

PART III: HU USE

1. Was the pateint prescribed HU at any time during this interval?
 - A. If yes, what was the:
 1. Dose at the first time it was prescribed this interval:

HU_PRESCRIBED

HU_DOSE_WEIGHT

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- 2. Dose form
- 2. Was the patient still being prescribed HU at the end of the interval?
 - A. If yes, what was the:
 - 1. Dose at the end of the interval
 - 2. Dose form
 - B. If No, what was the date the patient stopped being prescribed HU?
- 3. Did the patient have HU held because of possible drug toxicity during this interval?
 - A. If Yes, check all that apply:
 - 1. Low ANC
 - 2. Low Hgb
 - 3. Low PHs
 - 4. Other bacterial or viral infection
 - 5. Other
 - a. If Other, specify:
- 4. Estimate how many weeks during this interval the patient actually took HU:

HU_DOSE_FORM
HU_INTERVAL_END

HU_DOSE_WEIGHT2
HU_DOSE_FORM2
HU_END_DT
HU_TOXICITY

LOW_ANC
LOW_HGB
LOW_PHS
OTHER_INFECTION
OTHER_TOXICITY_FTR
HU_TOXICITY_SP
HU_TREAT_WEEKS

This is the number of weeks HU was taken minus the number of weeks HU was stopped due to toxicity, if applicable. If there was no toxicity, it is the number of weeks HU was taken in this time period.

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PART IV: BLOOD RESULTS

1. Were any blood specimens collected for clinical reasons during this interval?

BLOOD_COLLECT
BLOOD_COLLECT_REAS ON

A. If No, reason

If No, Skip to Part V.

2. First CBC in interval:

A. Date:

FIRST_CBC_DT

B. Hemoglobin

FIRST_HEMGLOBIN

C: MCV

FIRST_MCV

D. Reticulocyte (% of RBC)

FIRST_RETIC_CNT

FIRST_RETIC_NOT_DONE

E. White Blood Cell Count

FIRST_WBC_ACOUNT

F. Absolute Neutrophil Count

FIRST_NEUTROPHIL_CNT

FIRST_NEUTROPHIL_NOT_DONE

G. Platelet Count

FIRST_PLATELETS_CNT

H. Red Blood Cell Count

FIRST_RBC

3. Last CBC in interval:

A. Date:

LAST_CBC_DT

LAST_CBC_NOT_DONE

B. Hemoglobin

LAST_HEMGLOBIN

C. MCV

LAST_MCV

D. Reticulocyte (% of RBC)

LAST_RETIC_CNT

LAST_RETIC_NOT_DONE

E. White Blood Cell Count

LAST_WBC_ACOUNT

F. Absolute Neutrophil Count

LAST_NEUTROPHIL_CNT

LAST_NEUTROPHIL_NOT_DONE

G. Platelet Count

LAST_PLATELETS_CNT

H. Red Blood Cell Count

LAST_RBC

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4. Were any of the following laboratory values obtained during this interval?

*A. If No, reason:

1. If Other, specify:

*If No, Skip to Part V.

B. Creatinine:

1. Date:

2. Value:

C. ALT

1. Date:

2. Value:

D. GGT

1. Date:

2. Value:

E. Fetal Hemoglobin:

1. Date:

2. Value:

LAB_VALUES	
NO_LAB_REASON	
NOLAB_REASON_SP	

CREATININE_DT	CRATININE_NOT_DONE
CRATININE_VALUE	

ALT_DT	ALT_NOT_DONE
ALT_VALUE	

GGT_DT	GGT_NOT_DONE
GGT_VALUE	

FETAL_HEMOGLOBIN_DT	FETAL_NOT_DONE
FETAL_HEMO_VAL	

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PART V: IMAGING RESULTS

1. Were any TCDs performed during this interval?:

TCD_IMAGE_RESULTS

If No, skip to Part V, 4

	TCD Date:	TCD Result:
1	TCD_DT	TCD_RESULT

COMPLETE TRANSMITTAL FORM 105 AND FAX ALONG WITH A COPY
OF ALL TCD REPORTS TO THE MEDICAL COORDINATING CENTER.

**Baby hug Follow-up Study (BHFS)
CLINICAL DATA REPORT**

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2. MRI Date

MRI_DT	MRI_NOT_DONE
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A. if MRI done, result:

CHECK THE MOST SEVERE RESULT

MRI_RESULTS

1. If Other, specify

MRI_RESULTS_SP

COMPLETE TRANSMITTAL FORM 105 AND FAX ALONG
WITH A COPY OF THE REPORT TO THE MEDICAL
COORDINATING CENTER.

3. MRA Date

MRA_DT	MRA_NOT_DONE
---------------	---------------------

A. If MRA done, any result abnormal?

MRA_ABNORMAL

COMPLETE TRANSMITTAL FORM 105 AND FAX ALONG
WITH A COPY OF THE REPORT TO THE MEDICAL
COORDINATING CENTER.

4. CT Date

CT_DT	CT_NOT_DONE
--------------	--------------------

A. If CT done, any result abnormal?

CT_ABNORMAL

COMPLETE TRANSMITTAL FORM 105 AND FAX ALONG
WITH A COPY OF THE REPORT TO THE MEDICAL
COORDINATING CENTER.

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CLINICAL DATA REPORT**

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PART VI: OTHER PROCEDURES

1. EEG Date

A. If EEG done, any result abnormal?

EEG_DT	EEG_NOT_DONE
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EEG_ABNORMAL	
---------------------	--

2. PFTs Date

A. If Pulmonary Function Tests done, any result abnormal?

PFTS_DT	PFTS_NOT_DONE
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PFTS_ABNORMAL	
----------------------	--

3. Neuropsych Date

A. If neuropsychology testing done, any result abnormal?

NEUROPSYCH_DT	NEUROPSYCH_NOT_DONE
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NEUROPSYCH_ABNORMAL	
----------------------------	--

1. Specify test:

NEUROPSYCH_SP	
----------------------	--

COMPLETE TRANSMITTAL FORM 105 AND FAX ALONG
WITH A COPY OF THE REPORT TO THE MEDICAL
COORDINATING CENTER.

4. Other clinical tests done:

A. If Yes, specify

OTHER_TEST	
-------------------	--

OTHER_TEST_SP	
----------------------	--

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PART VII: CLINICAL EVENTS

1. Clinic Visits

A. During this interval how many times was this patient seen in clinic (not ER, day unit, or hospital)?

CLINIC_VISITS

If zero, Skip to Part VII Item 2

B. Enter the number of visits for which the following were the main reasons for each visit in this time period:

1. Routine Clinical Visit (physical examination by sickle cell team)
2. HU toxicity assessment (blood count check to monitor HU therapy and possible side effects)
3. Other clinical service (including follow-up of crisis event and general pediatrics)
4. Other
 - a. If Other, specify:

PERIODIC_CLIN_VIS
HU_TOXICITY_ASSESS4
OTHER_VISITS
OTHER_VISITS_2
OTHER_VISITS_SP

2. Hospitalization

A. How many times was this patient seen in an ER or day hospital during this interval (in your facility or another):

ER_VISITS

If zero, Skip to Part VII Item 3

B. Reasons for visits:

1. Acute splenic sequestration crisis
2. Acute chest syndrome
3. Neurologic event (stroke or seizure)
4. Aplastic Crisis
5. Urinary tract infection
6. Fever or febrile illness including URI/sinusitis/cold/flu

ACUTE_SPLENIC_SEQUE S
ACUTE_CHEST_SYNDRO ME
STROKE_SEIZURE
APLASTIC_CRISIS
URINARY_TRACT_INFECT
FEVER_FEBRILE

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- 7. Other acute illness, no fever
- 8. Trauma including broken bones and sprains
- 9. Sickle Cell Pain Crisis (including dactylitis)
- 10. Other
 - a. If Other, specify:

NO_FEVER
TRAUMA
PAIN
OTHER_CRISIS
OTHER_CRISIS_SP
HOSPITAL_TIMES

3. How many times was the patient admitted to the hospital during this interval (in your facility or another)?

If zero, Skip to Part VII Item 4

A. What was the primary discharge diagnosis for each of these admissions?

- 1. Neurologic event (stroke or seizure)
- 2. Acute splenic sequestration crisis
- 3. Acute chect syndrome
- 4. Aplastic Crisis
- 5. Urinary tract infection
- 6. Fever or febrile illness including URI/sinusitis/cold/flu
- 7. Other acute illness, no fever
- 8. Trauma including broken bones and sprains
- 9. Sickle Cell Pain Crisis (including dactylitis)
- 10. Surgery (see part VII, item 5 below)
- 11. Other:
 - a. If Other, specify:

DIAGNOSIS_STROKE
DIAG_SPENIC_SEQUES
DIAGNOSIS_CHEST
DIAGNOSIS_APLASTIC
DIAGNOSIS_URINARY
DIAGNOSIS_FEVER
DIAGNOSIS_NO_FEVER
DIAGNOSIS_TRAUMA
DIAGNOSIS_PAIN
DIAGNOSIS_SURGERY
DIAGNOSIS_OTHER
DIAGNOSIS_OTHER_SP

**Baby hug Follow-up Study (BHFS)
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4. Pain

A. Has the child experienced pain (defined as pain lasting four hours or more without other obvious cause for which medication such as ibuprofen, acetaminophen, or acetaminophen with opioid was taken for relief) even if not seen by a medical professional during the interval?

1. If yes, how many episodes of pain has the patient experienced during this interval?

PAIN2
PAIN_EPISODES

5. Surgery

A. Did the patient have at least one surgery during this interval?

1. If yes, identify the type of each surgery and give date:

a. Tonsillectomy, Adenoidectomy or both

Date:

b. Splenectomy (open or laproscopic)

Date:

c. Cholecystectomy and/or ERCP

Date:

d. Ear tubes, hernia repair, dental rehabilitation

Date:

e. Other

1. If Other, specify

SURGERY

TONSILLECTOMY_ND
TONSILLECTOMY_DT
SPLENECTOMY_NOT_DONE
SPLENECTOMY_DT
CHOLECYSTECTOMY_ND
CHOLECYSTECTOMY_DT
EAR_NOT_DONE
EAR_DT
SURGERY_OTHER
SURGERY_OTHER_SP

**Baby hug Follow-up Study (BHFS)
CLINICAL DATA REPORT**

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Revision 4

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6. Transfusion

A. Was the patient on a chronic transfusion program during this interval (meaning scheduled transfusions every two-six weeks for three months or more)?

1. If yes, what was the main reason for the chronic transfusion program:

a. If Other, specify:

B. Did the patient receive an episodic transfusion during this interval (meaning a transfusion, scheduled or not that was for a specific problem or to prepare them for surgery)?

1. If yes, what was the main reason for the episodic transfusion?

a. If Other, specify:

CHRONIC_TRANSFUSION
CHRONIC_TRANS_REASON
CHRONIC_TRANS_SP
EPISODIC_TRANSFUSION
EPISODIC_TRANS_RSN
EPISODIC_TRANS_SP

**Baby hug Follow-up Study (BHFS)
CLINICAL DATA REPORT**

Form 010
Revision 4

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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PART VIII: PHYSICAL EXAMINATION

If there are more than three sets of collected physical examination data, use the first and last in the sequence and select the one closest in days to the midpoint of the interval. Sickle Cell or Hematology clinic examinations are preferred over ER/hospital/general pediatric visits if there is a choice.

1. Was a physical examination performed during this interval?

PHISICAL_EXAM

If No, Skip to Part IX

2. Growth Parameters:

A. First Encounter

Date:	FIRST_ENCOUNTER_DT
1. Height	FIRST_HEIGHT FIRST_HEIGHT_NOTDONE
2. Weight	FIRST_WEIGHT FIRST_WEIGHT_NOTDONE
3. Head Circumference	FIRST_HEAD_CIRCUM FIRST_HEAD_NOTDONE

B. Second Encounter (mid-point)

Date:	SECOND_ENCOUNTER_DT	SECOND_ENCOUNTER_ND
-------	----------------------------	----------------------------

If Not Done, Skip to Part VIII, Item 2C

1. Height
2. Weight
3. Head Circumference

SECOND_HEIGHT	SECOND_HEIGHT_ND
SECOND_WEIGHT	SECOND_WEIGHT_ND
SECOND_HEAD_CIRCUM	SECOND_HEAD_NOTDONE

C. Last or latest Visit

Date:	LAST_ENCOUNTER_DT	LAST_ENCOUNTER_ND
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If Not Done, Skip to Part VIII, Item 3

1. Height
2. Weight
3. Head Circumference

LAST_HEIGHT	LAST_HEIGHT_NOTDONE
LAST_WEIGHT	LAST_WEIGHT_NOTDONE
LAST_HEAD_CIRCUM	LAST_HEAD_NOTDONE

**Baby hug Follow-up Study (BHFS)
CLINICAL DATA REPORT**

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3. A. Was the spleen reported to be palpable below the costal margin at any time during this interval?

SPLEEN_PALPABLE

If No, Skip to Part IX

B. On what date was it the largest (most centimeters below costal margin)

SPLEEN_LARGEST_DT

Write the largest value below:

1. Mid-clavicular line

MID_CLAVICULAR	MID_CLA_NOTDONE
-----------------------	------------------------

2. Anterior axillary line

ANTEROR_AXILLARY	ANT_AXI_NOTDONE
-------------------------	------------------------

C. Was the child diagnosed with acute splenic sequestration during this interval?

DIAG_SPLENIC_SEQU

PART IX: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

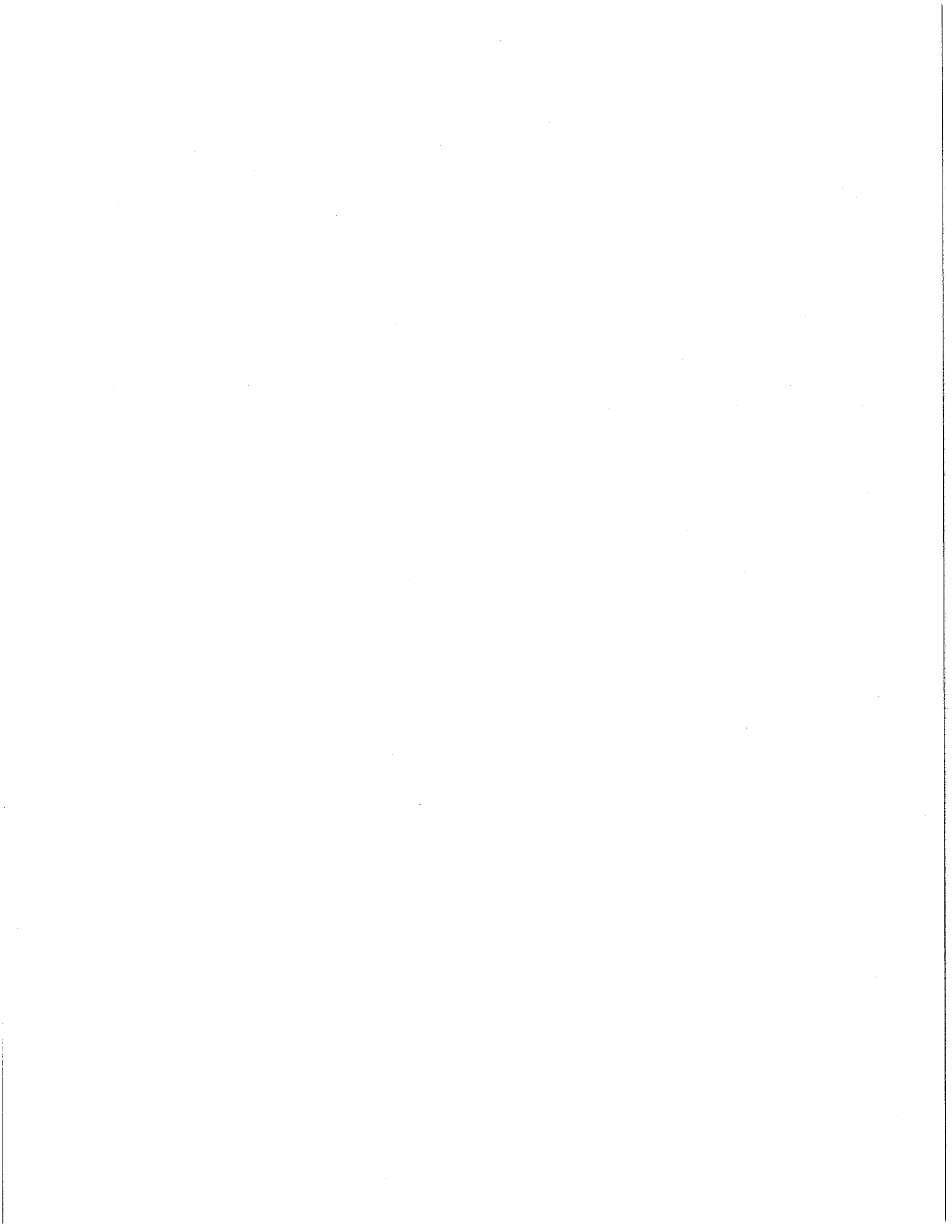
CERT_NO

B. Signature

CERT_SIG

C. General Comments

GEN_CMNT



**Baby hug Follow-up Study (BHFS)
48-MONTH OR EXIT LABORATORY TESTS**

Form 011
Revision 1

Tue Sep 22 10:21:34 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: SPECIAL TESTS AND PROCEDURES

1. Urine Microalbumin: Creatinine (5 ml):

A. Label Number:

URINE_LABEL_NUM	URINE_LABEL
------------------------	--------------------

B. Date Collected:

URINE_DT	
-----------------	--

2. Stored Blood Sample (5 ml EDTA lavender top):

A. Label Number:

BLOOD_LABEL_NUM	BLOOD_LABEL
------------------------	--------------------

B. Date Collected:

BLOOD_DT	
-----------------	--

3. VDJ/HJB (3 ml EDTA lavender top):

A. Label Number:

VDJ_LABEL_NUM	VDJ_LABEL
----------------------	------------------

B. Date Collected:

VDJ_DT	
---------------	--

Baby hug Follow-up Study (BHFS)
48-MONTH OR EXIT LABORATORY TESTS

Form 011

Revision 1

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4. Pitted Cell (0.1 ml EDTA gluteraldehyde):

A. Label Number:

CELL_LABEL_NUM	CELL_LABEL
-----------------------	-------------------

B. Date Collected:

CELL_DT

5. Cystatin C (0.5 ml red top):

A. Label Number:

CYSTATIN_LABEL_NUM	CYSTATIN_LABEL
---------------------------	-----------------------

B. Date Collected:

CYSTATIN_DT

6. Creatinine (0.5 ml red top):

A. Label Number:

CREATININE_LABEL_NUM	CREATININE_LABEL
-----------------------------	-------------------------

B. Date Collected:

CREATININE_DT

PART III: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

CERT_NO

B. Signature

CERT_SIG

C. General Comments

GEN_CMNT

**Baby hug Follow-up Study (BHFS)
EXIT FORM**

Form 012
Revision 1

Tue Sep 22 10:22:17 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: END OF TREATMENT

1. End of Follow-up Participation

A. Planned end of follow-up participation

If Yes, skip to Part III.

END_PARTICIPATION

B. Reason for study exit:

- 1. Inactive follow-up status
- 2. Permanent relocation to area with no BABY HUG Clinic
- 3. Withdrew consent
- 4. Death
- 5. Other condition requiring end of participation

INACTIVE
RELOCATION
WITHDRAW
DEATH
OTHER
OTHER_SP
LAST_CONTACT_DT

a. If Yes, specify:

2. Date of last contact with family:

Baby hug Follow-up Study (BHFS)
EXIT FORM

Form 012
Revision 1

Tue Sep 22 10:22:17 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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PART III: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number:
- B. Signature
- C. General Comments

CERT_NO
CERT_SIG
GEN_CMNT

**Baby hug Follow-up Study (BHFS)
24 MONTH TRANSCRANIAL (TCD) EXAM**

Form 013
Revision 1

Tue Sep 22 10:22:53 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

Part II: EQUIPMENT

- 1. TCD Examiner's last name
- 2. Patient's position during exam
 - A. SPECIFY

RDR46
PTNTPOS
POS_SP

Part III: EXAMINATION PERFORMANCE

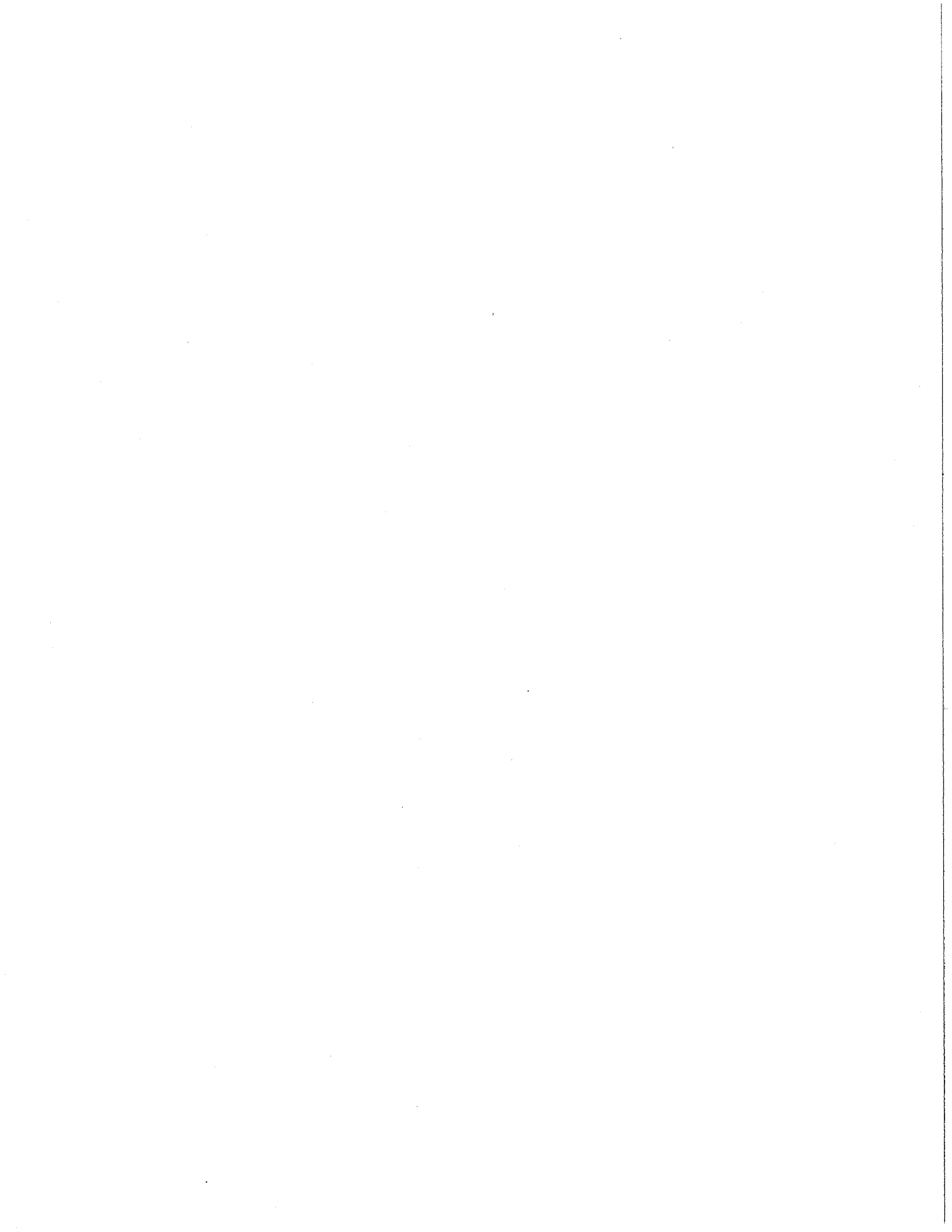
- 1. Completeness of exam
 - A. Reason for incomplete exam
 - 1. Specify
 - B. TCD Label

COMPEXAM
INCEXAM
INCEX_SP
TCD_LBL

Part IV: COORDINATION

- 1. Checked for completeness and accuracy:
 - A. Certification number:
 - B. Signature
 - C. General Comments

CERT_NO
CERT_SIG
GEN_CMNT



Baby hug Follow-up Study (BHFS)
24_MONTH SPECIAL TESTS AND LABORATORY TESTS (Active Patients Only)

Form 020
Revision 2

Tue Sep 22 10:25:44 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: BLOOD COLLECTION

1. Were blood specimens collected as part of active follow-up?

BLOOD_COLLECT

If No, skip to Part III.

2. HbF (0.5 ml EDTA lavender top):

A. Label Number:

HBF_LABEL	HBF_LABEL_ND
------------------	---------------------

B. Date Collected:

HBF_DT

3. Howell-Jolly Bodies (0.1ml EDTA lavender top):

A. Label Number:

HOWELL_LABEL	HOWELL_LABEL_ND
---------------------	------------------------

B. Date Collected:

HOWELL_DT

24_MONTH SPECIAL TESTS AND LABORATORY TESTS (Active Patients Only)

Tue Sep 22 10:25:44 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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4. Pitted Cell (0.1 ml EDTA lavender top):

A. Label Number:

CELL_LABEL	CELL_LABEL_ND
-------------------	----------------------

B. Date Collected:

CELL_DT

5. Cystatin C (0.5 ml red top):

A. Label Number:

CYSTATIN_LABEL	CYSTATIN_LABEL_ND
-----------------------	--------------------------

B. Date Collected:

CYSTATIN_DT

6. Creatinine (0.5 ml red top):

A. Label Number:

CREATININE_LABEL	CREATININE_LABEL_ND
-------------------------	----------------------------

B. Date Collected:

CREATININE_DT

PART III: SPECIAL TESTS AND PROCEDURES

1. Liver/Spleen Scan Performed?

LIVER_SCAN

If Yes, record date performed and complete Form 21.

A. Date Performed:

Baby hug Follow-up Study (BHFS)
24_MONTH SPECIAL TESTS AND LABORATORY TESTS (Active Patients Only)

Form 020
Revision 2

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2. Abdominal Sonogram Performed?

ABDOMINAL_SONO

If Yes, record date performed and complete Form 23.

A. Date Performed:

ABDOMINAL_SONO_DT

3. Neuropsychology Testing (WPPSI) Performed?

NEUROPSYCH_TEST

If Yes, record date performed and complete Form 24.

A. Date Performed:

NEUROPSYCH_DT

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number:

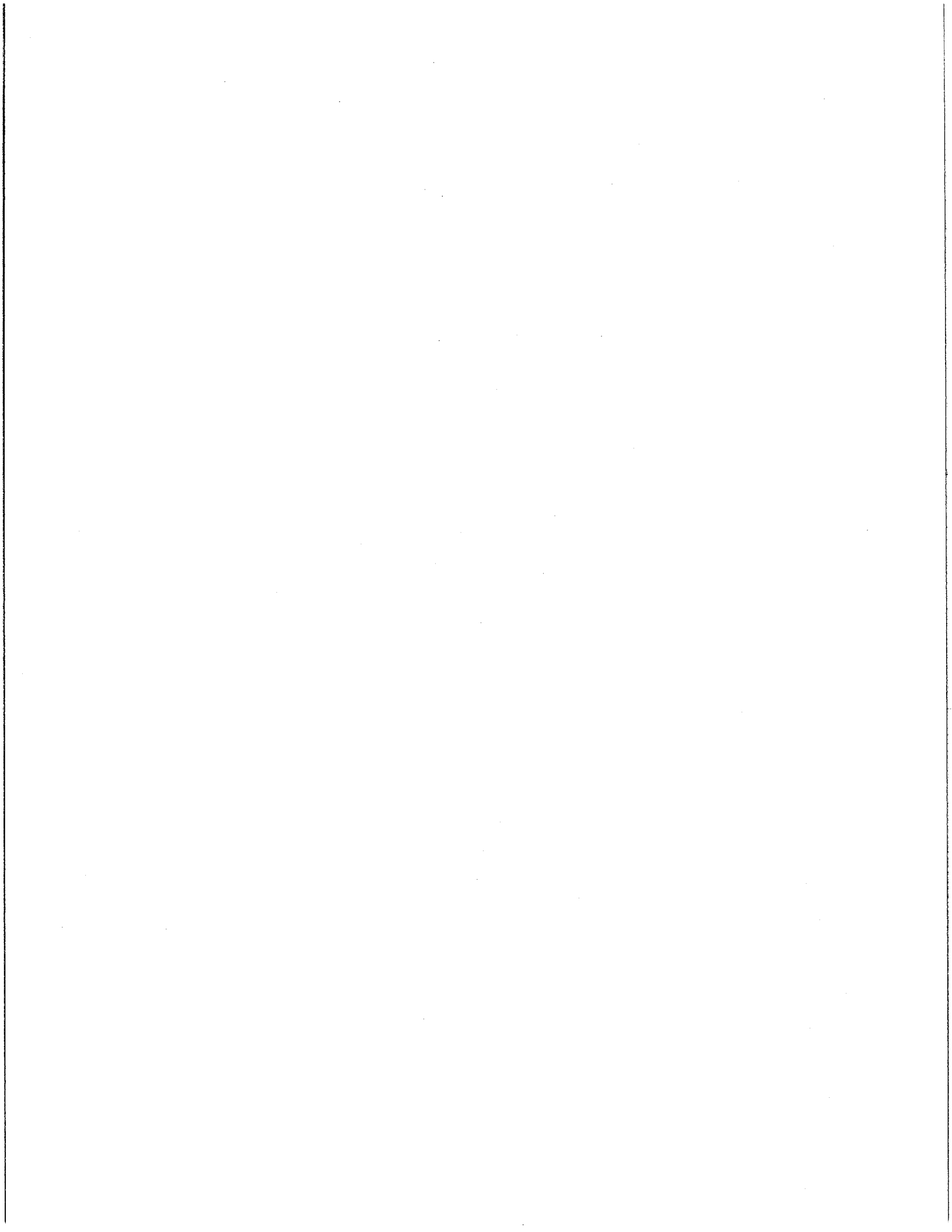
CERT_NO

B. Signature

CERT_SIG

C. General Comments

GEN_CMNT



**Baby hug Follow-up Study (BHFS)
LIVER-SPLEEN SCAN PERFORMANCE**

Form 021

Revision 1

Tue Sep 22 10:26:53 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: SCAN SPECIFICS

1. Camera manufacturer:
2. Camera Model:
3. Collimator:
4. Supplier of TC-sulfur colloid:
5. Dose injected:
6. Time of injection (24-hour clock)
7. Time imaging started
8. Time imaging completed
9. Camera angle:
10. True Posterior imaging time (min:sec)
11. Right Posterior Oblique Image Counts:
12. Film Label:
13. Adequacy of imaging (answer both questions)
 - A. 400 K Image adequate?
 - B. Timed Image adequate?

CAMTYPE	
CAMMODEL	
COLLIMAT	
SUPCOLLD	
DOSINJ44	
INJ44HR	INJ44MN
IMSTRHR	IMSTRMN
IMCOMHR	IMCOMMN
CAMANGLE	
ANTPOSMN	ANTPOSSC
OBLIMCNT	
LSSCNLBL	
AOI400K	
AOITIMED	

**Baby hug Follow-up Study (BHFS)
LIVER-SPLEEN SCAN PERFORMANCE**

Form 021
Revision 1

Tue Sep 22 10:26:53 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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Part III: Quantitative Assessment

1. 400K image

A. Anterior View

1. Spleen

counts	a. Total	KASPLTOT
ROI	b. # Pixels in	KASPLPIX
Counts/pixel	c.	KASPLCNT

2. Liver

counts	a. Total	KALIVTOT
ROI	b. # Pixels in	KALIVPIX
Counts/pixel	c.	KALIVCNT

B. Posterior View

1. Spleen

counts	a. Total	KPSPLTOT
ROI	b. # Pixels in	KPSPLPIX
Counts/pixel	c.	KPSPLCNT

2. Liver

counts	a. Total	KPLIVTOT
ROI	b. # Pixels in	KPLIVPIX
Counts/pixel	c.	KPLIVCNT

C. Spleen/Liver Ratio

1. Total counts	KSLRTTOT
2. Counts/pixel	KSLRTCNT

**Baby hug Follow-up Study (BHFS)
LIVER-SPLEEN SCAN PERFORMANCE**

Form 021

Revision 1

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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2. Timed image

A. Left Anterior
Oblique View

1. Spleen

counts	a. Total	TASPLTOT
ROI	b. # Pixels in	TASPLPIX
Counts/pixel	c.	TASPLCNT

2. Liver

counts	a. Total	TALIVTOT
ROI	b. # Pixels in	TALIVPIX
Counts/pixel	c.	TALIVCNT

B. Right Posterior
Oblique View

1. Spleen

counts	a. Total	TPSPLTOT
ROI	b. # Pixels in	TPSPLPIX
Counts/pixel	c.	TPSPLCNT

2. Liver

counts	a. Total	TPLIVTOT
ROI	b. # Pixels in	TPLIVPIX
Counts/pixel	c.	TPLIVCNT

C. Spleen/Liver Ratio

1. Total counts	TSLRTTOT
2. Counts/pixel	TSLRTCNT

Baby hug Follow-up Study (BHFS)
LIVER-SPLEEN SCAN PERFORMANCE

Form 021
Revision 1

Tue Sep 22 10:26:53 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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Part IV: Examiner

- 1. Examiner name:
- 2. Signature:

EXAMINER_NM
SIGNATURE

PART V: COORDINATION

- 1. Checked for completeness and accuracy:
 - A. Certification number:
 - B. Signature
 - C. General Comments

CERT_NO
CERT_SIG
GEN_CMNT

**Baby hug Follow-up Study (BHFS)
DTPA/GFR**

Form 022
Revision 2

Tue Sep 22 10:27:38 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: ANTHROPOMETRICS

- 1. Height
- 2. Weight

HEIGHT	cm
WEIGHT	kg

PART III: DTPA MEASUREMENTS

- 1. Standard syringe activity
 - A. Pre
 - B. Post
 - C. Standard Activity

STSAPRE	mCi
STSAPOST	mCi
STSASTAC	mCi

- 2. Dose syringe activity

- A. Pre
- B. Post
- C. Dose Administered
- D. Time DTPA administered

DSSAPRE	mCi
DSSAPOST	mCi
DTPADOSE	mCi
DTPAHR	DTPAMN

**Baby hug Follow-up Study (BHFS)
DTPA/GFR**

Form 022
Revision 2

Tue Sep 22 10:27:38 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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3. Room (water) background

A. First count:	ROOMFRST cpm	
B. Second count:	ROOMSEC cpm	ROOMSCND

4. Standard

A. First count:	STNDFRST cpm	
B. Second count:	STNDSEC cpm	STNDSCND

5. A. One-hour time (24-hr. clock)

ONEHR	ONEMN	
--------------	--------------	--

B. DTPA measurement	ONEDTPA cpm	ONE_ND
---------------------	--------------------	---------------

C. Second DTPA measurement

ONEDTPA2 cpm	ONE_ND2
---------------------	----------------

6. A. Two-hour time (24-hr. clock)

TWOHR	TWOMN	
--------------	--------------	--

B. DTPA measurement	TWODTPA cpm	TWO_ND
---------------------	--------------------	---------------

C. Second DTPA measurement

TWODTPA2 cpm	TWO_ND2
---------------------	----------------

7. A. Four-hour time (24-hr. clock)

FORHR	FORMN	
--------------	--------------	--

B. DTPA measurement	FORDTPA cpm	FOR_ND
---------------------	--------------------	---------------

C. Second DTPA measurement

FORDTPA2 cpm	FOR_ND2
---------------------	----------------

8. GFR from DTPA

A. GFR:	GFRDTP_A ml/min
B. GFR:	GFRDTP_B ml/min/m ²
C. GFR	GFRDTP_C ml/min/1.73m ²

**Baby hug Follow-up Study (BHFS)
DTPA/GFR**

Form 022
Revision 2

Tue Sep 22 10:27:38 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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Part IV: TECHNICIAN

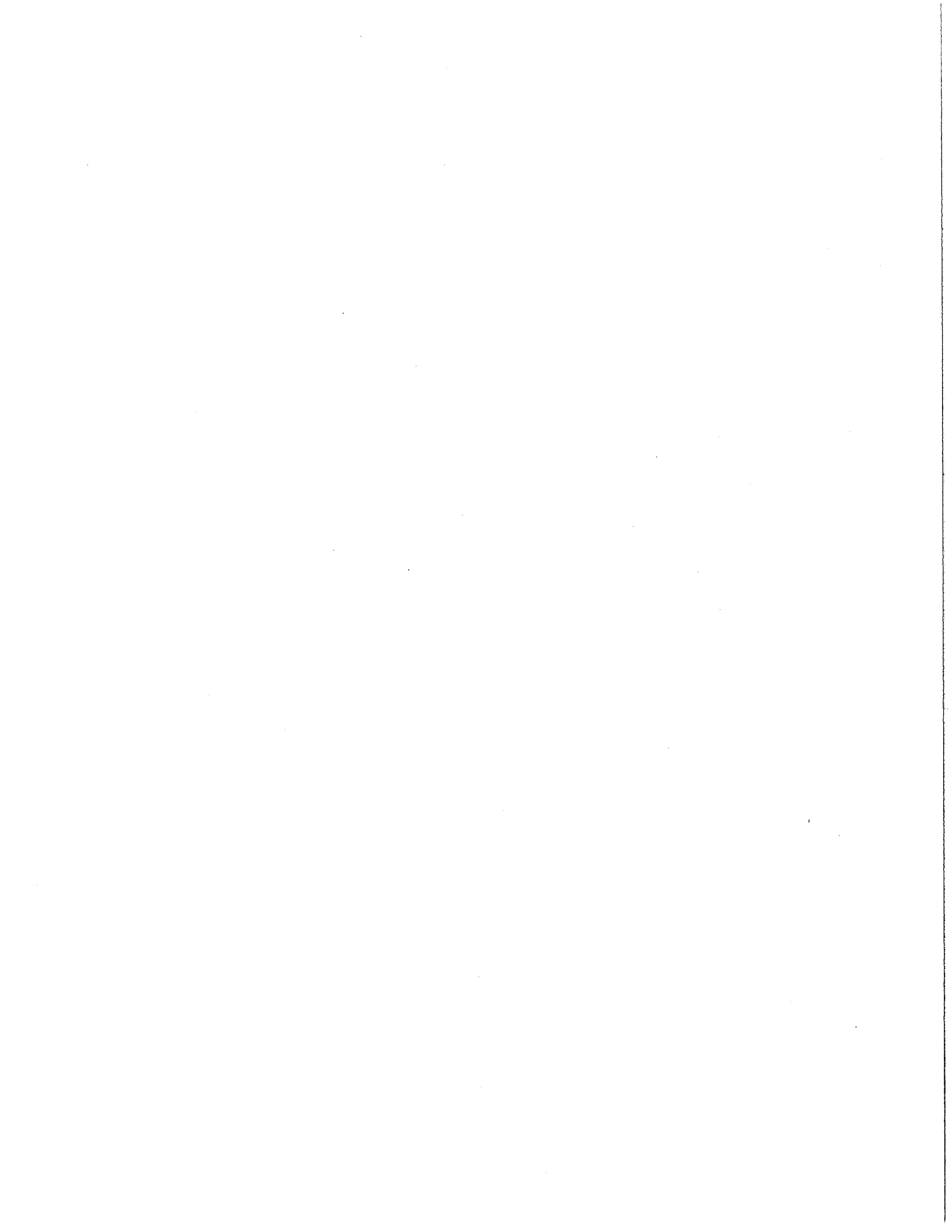
- 1. Technician Name:
- 2. Signature:

EXAMINER_NM
SIGNATURE

PART V: COORDINATION

- 1. Checked for completeness and accuracy:
 - A. Certification number:
 - B. Signature
 - C. General Comments

CERT_NO
CERT_SIG
GEN_CMNT



Baby hug Follow-up Study (BHFS)
ABDOMINAL SONOGRAM (ULTRASOUND) PERFORMANCE

Form 023
Revision 1

Tue Sep 22 10:28:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: EQUIPMENT AND QUALITY

1. Equipment
2. Transducer
3. Quality of study
4. Film label

ABDSEQPT
ABDSTRNS
STATUS45
SONO_LBL

PART III: Sonographer

1. Sonographer's name:
2. Signature:

EXAMINER_NM
SIGNATURE

Baby hug Follow-up Study (BHFS)
ABDOMINAL SONOGRAM (ULTRASOUND) PERFORMANCE

Form 023

Revision 1

Tue Sep 22 10:28:18 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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PART IV: COORDINATION

1. Checked for completeness and accuracy:

- A. Certification number:
- B. Signature
- C. General Comments

CERT_NO
CERT_SIG
GEN_CMNT

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

Form 024
Revision 3

Tue Sep 22 10:31:37 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Visit Date: VISIT_DT

PART II: SUBTEST SCORING

1. Block Design (Discontinue testing after 3 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. 4 Red

BD_1

11. 4 two-color

BD_11

2. 6 Red

BD_2

12. 4 two-color

BD_12

3. 6 Red

BD_3

13. 4 two-color

BD_13

4. 4 Red

BD_4

14. 4 two-color

BD_14

5. 2 Red, 2 White

BD_5

15. 4 two-color

BD_15

6. 4 Red, 2 White

BD_6

16. 4 two-color

BD_16

7. 2 Red, 2 White

BD_7

17. 4 two-color

BD_17

8. 6 Red

BD_8

18. 4 two-color

BD_18

9. 4 Red, 4 White

BD_9

19. 4 two-color

BD_19

10. 4 Red, 4 White

BD_10

20. 4 two-color

BD_20

B. Total Raw Score

BD_SCORE

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

Form 024
Revision 3

Tue Sep 22 10:31:37 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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2. Information (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Eat	INFO_1	12. Ears	INFO_12	23. Chew	INFO_23
2. Bath	INFO_2	13. Paper	INFO_13	24. Vegetable	INFO_24
3. Drink	INFO_3	14. Bottle	INFO_14	25. Letter	INFO_25
4. Meow	INFO_4	15. Finger	INFO_15	26. Saturday	INFO_26
5. Cut	INFO_5	16. Rainbow	INFO_16	27. Shoes	INFO_27
6. Water	INFO_6	17. Legs	INFO_17	28. Week	INFO_28
7. Nose	INFO_7	18. Animals	INFO_18	29. Seasons	INFO_29
8. Knee	INFO_8	19. Gives milk	INFO_19	30. Opposite	INFO_30
9. Old	INFO_9	20. Rain	INFO_20	31. Bread	INFO_31
10. Write	INFO_10	21. Shines	INFO_21	32. Milk	INFO_32
11. Grass	INFO_11	22. Wheels	INFO_22	33. Ocean	INFO_33
				34. Sun	INFO_34
					INFO_SCORE

B. Total Raw Score

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

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3. Matrix Reasoning (Discontinue testing after 4 consecutive scores of 0, or 4 scores of 0 on 5 consecutive items.)

A. Record form Data. Choose one response for each question.

1.	MR_1
2.	MR_2
3.	MR_3
4.	MR_4
5.	MR_5
6.	MR_6
7.	MR_7
8.	MR_8
9.	MR_9
10.	MR_10

11.	MR_11
12.	MR_12
13.	MR_13
14.	MR_14
15.	MR_15
16.	MR_16
17.	MR_17
18.	MR_18
19.	MR_19
20.	MR_20

21.	MR_21
22.	MR_22
23.	MR_23
24.	MR_24
25.	MR_25
26.	MR_26
27.	MR_27
28.	MR_28
29.	MR_29

B. Total Raw Score

MR_SCORE

4. Vocabulary (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Car	VOC_1
2. Clock	VOC_2

3. Fork	VOC_3
4. Turtle	VOC_4

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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5. Pumpkin	VOC_5	16. Castle	VOC_16
6. Shoe	VOC_6	17. Glow	VOC_17
7. Telephone	VOC_7	18. Polite	VOC_18
8. Umbrella	VOC_8	19. Holiday	VOC_19
9. Bicycle	VOC_9	20. Swing	VOC_20
10. Candy	VOC_10	21. Double	VOC_21
11. Dog	VOC_11	22. Courage	VOC_22
12. Letter	VOC_12	23. Ancient	VOC_23
13. Train	VOC_13	24. Microscope	VOC_24
14. Leaf	VOC_14	25. Nuisance	VOC_25
15. Hero	VOC_15		
B. Total Raw Score			VOC_SCORE

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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5. Picture Concepts (Discontinue testing after 4 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1.	PCON_1	11.	PCON_11	21.	PCON_21
2.	PCON_2	12.	PCON_12	22.	PCON_22
3.	PCON_3	13.	PCON_13	23.	PCON_23
4.	PCON_4	14.	PCON_14	24.	PCON_24
5.	PCON_5	15.	PCON_15	25.	PCON_25
6.	PCON_6	16.	PCON_16	26.	PCON_26
7.	PCON_7	17.	PCON_17	27.	PCON_27
8.	PCON_8	18.	PCON_18	28.	PCON_28
9.	PCON_9	19.	PCON_19		
10.	PCON_10	20.	PCON_20		

PCON_SCORE

B. Total Raw Score

6. Symbol Search (Discontinue testing after 120 seconds.)

A. Total Raw Score

SS_SCORE

7. Word Reasoning (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1.	WR_1	11.	WR_11	21.	WR_21
2.	WR_2	12.	WR_12	22.	WR_22
3.	WR_3	13.	WR_13	23.	WR_23
4.	WR_4	14.	WR_14	24.	WR_24
5.	WR_5	15.	WR_15	25.	WR_25
6.	WR_6	16.	WR_16	26.	WR_26
7.	WR_7	17.	WR_17	27.	WR_27
8.	WR_8	18.	WR_18	28.	WR_28
9.	WR_9	19.	WR_19		
10.	WR_10	20.	WR_20		

WR_SCORE

B. Total Raw Score

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8. Coding (Discontinue testing after 120 seconds.)

A. Total Raw Score

COD_SCORE

9. Comprehension (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Stove

CMPHN_1

11. Share

CMPHN_11

2. Street

CMPHN_2

12. Names

CMPHN_12

3. Thank you

CMPHN_3

13. Take turns

CMPHN_13

4. Hands

CMPHN_4

14. On time

CMPHN_14

5. Shoes

CMPHN_5

15. Line

CMPHN_15

6. School

CMPHN_6

16. Permission

CMPHN_16

7. Babysitters

CMPHN_7

17. Water

CMPHN_17

8. Strangers

CMPHN_8

18. Shots

CMPHN_18

9. Home

CMPHN_9

19. Buses and trains

CMPHN_19

10. Tags

CMPHN_10

20. Vote

CMPHN_20

B. Total Raw Score

CMPHN_SCORE

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

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Revision 3

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10. Picture Completion (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Boy
2. Doll
3. Blocks
4. Jacket
5. Tricycle
6. Chair
7. Rose
8. Screws
9. Apple
10. Clothesline
11. Gloves
12. Kites
13. Boat
14. Clock
15. Ruler
16. Smile

PCOMP_1
PCOMP_2
PCOMP_3
PCOMP_4
PCOMP_5
PCOMP_6
PCOMP_7
PCOMP_8
PCOMP_9
PCOMP_10
PCOMP_11
PCOMP_12
PCOMP_13
PCOMP_14
PCOMP_15
PCOMP_16

17. Duck
18. Lunchbox
19. Swings
20. Door
21. Braids
22. Skating
23. Power lines
24. Desk
25. Car
26. Fishing
27. Coat
28. Ponytail
29. Hand
30. House
31. Clown
32. Rooster

PCOMP_17
PCOMP_18
PCOMP_19
PCOMP_20
PCOMP_21
PCOMP_22
PCOMP_23
PCOMP_24
PCOMP_25
PCOMP_26
PCOMP_27
PCOMP_28
PCOMP_29
PCOMP_30
PCOMP_31
PCOMP_32
PCOMP_SCORE

B. Total Raw Score

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

Form 024
Revision 3

Tue Sep 22 10:31:37 EDT 2015

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11. Similarities (Discontinue testing after 4 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Red and yellow
2. Cookies and ice cream
3. Juice and milk
4. Socks and shirts
5. Dogs and cats
6. Apples and oranges
7. Pencils and crayons
8. Dolls and balls
9. Two and three
10. Books and newspapers
11. Guitars and drums
12. Arms and legs

SIM_1
SIM_2
SIM_3
SIM_4
SIM_5
SIM_6
SIM_7
SIM_8
SIM_9
SIM_10
SIM_11
SIM_12

13. Mothers and sisters
14. Plates and bowls
15. Circles and squares
16. Cars and trucks
17. Ears and noses
18. Rain and snow
19. Buttons and zippers
20. Happy and sad
21. Tables and chairs
22. Sweet and sour
23. Heavy and light
24. Asleep and awake

SIM_13
SIM_14
SIM_15
SIM_16
SIM_17
SIM_18
SIM_19
SIM_20
SIM_21
SIM_22
SIM_23
SIM_24
SIM_SCORE

B. Total Raw Score

**Baby hug Follow-up Study (BHFS)
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12. Receptive Vocabulary (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Foot	RV_1	20. Curly tail	RV_20
2. Cup	RV_2	21. Cash Register	RV_21
3. Doll	RV_3	22. Telescope	RV_22
4. Butterfly	RV_4	23. Beneath tree	RV_23
5. Giraffe	RV_5	24. Cymbals	RV_24
6. Painting	RV_6	25. Fancy	RV_25
7. Toaster	RV_7	26. Shaggy	RV_26
8. Snail	RV_8	27. Balancing	RV_27
9. Raining	RV_9	28. Bulldozer	RV_28
10. Vacuum Cleaner	RV_10	29. Easel	RV_29
11. Basketball	RV_11	30. Gnawing	RV_30
12. Lamp	RV_12	31. Carousel	RV_31
13. Kicking	RV_13	32. Crouching	RV_32
14. Triangle	RV_14	33. Prancing	RV_33
15. Stirring	RV_15	34. Clenching	RV_34
16. Lying down	RV_16	35. Parallel	RV_35
17. Carrying	RV_17	36. Cylinder	RV_36
18. Desert	RV_18	37. Equivalent	RV_37
19. Paying	RV_19	38. Horizontal	RV_38
B. Total Raw Score			RV_SCORE

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

Form 024
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13. Object Assembly (Discontinue testing after 3 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

- 1. Ball
- 2. Hot dog
- 3. Bird
- 4. Clock
- 5. Car
- 6. Fish
- 7. Bear
- 8. Hand
- 9. House
- 10. Apple
- 11. Dog
- 12. Star

OA_1
OA_2
OA_3
OA_4
OA_5
OA_6
OA_7
OA_8
OA_9
OA_10
OA_11
OA_12

Baby hug Follow-up Study (BHFS)

Form 024

WPPSI FORM

Revision 3

Tue Sep 22 10:31:37 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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13. Calf

OA_13

14. Tree

OA_14

B. Total Raw Score

OA_SCORE

14. Picture Naming (Discontinue testing after 5 consecutive scores of 0.)

A. Record form Data. Choose one response for each question.

1. Car

PN_1

16. Guitar

PN_16

2. Bear

PN_2

17. Shell

PN_17

3. Banana

PN_3

18. Rake

PN_18

4. Star

PN_4

19. Nail

PN_19

5. Clock

PN_5

20. Lock

PN_20

6. Fork

PN_6

21. Ambulance

PN_21

7. Scissors

PN_7

22. Rhinoceros

PN_22

8. Turtle

PN_8

23. Iron

PN_23

9. Toothbrush

PN_9

24. Pineapple

PN_24

10. Pumpkin

PN_10

25. Teapot

PN_25

11. Ladybug

PN_11

26. Globe

PN_26

12. Broom

PN_12

27. Xylophone

PN_27

13. Whistle

PN_13

28. Thermometer

PN_28

14. Zebra

PN_14

29. Harp

PN_29

15. Kangaroo

PN_15

30. Fire extinguisher

PN_30

B. Total Raw Score

PN_SCORE

15. Child's Age at Testing

Years

AGE_YEARS

Months

AGE_MONTHS

Days

AGE_DAYS

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

Form 024
Revision 3

Tue Sep 22 10:31:37 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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16. Sums of Scaled Scores and Composite Score Conversions (Enter score in each box.)

A. Verbal IQ

1. Sum of Scaled Score	VIQ_SCALED		
2. Composite Score	VIQ_COMP		
3. Percentile Rank	VIQ_PERCENT		
4. Confidence Interval	VIQ_CONFINT	--	VIQ_CONFINT_HIGH

B. Performance IQ

1. Sum of Scaled Score	PIQ_SCALED		
2. Composite Score	PIQ_COMP		
3. Percentile Rank	PIQ_PERCENT		
4. Confidence Interval	PIQ_CONFINT	--	PIQ_CONFINT_HIGH

C. Processing Speed

1. Sum of Scaled Score	PS_SCALED		
2. Composite Score	PS_COMP		
3. Percentile Rank	PS_PERCENT		
4. Confidence Interval	PS_CONFINT	--	PS_CONFINT_HIGH

D. Full Scale IQ

1. Sum of Scaled Score	FSIQ_SCALED		
2. Composite Score	FSIQ_COMP		
3. Percentile Rank	FSIQ_PERCENT		
4. Confidence Interval	FSIQ_CONFINT	--	FSIQ_CONFINT_HIGH

E. General Language

1. Sum of Scaled Score	GL_SCALED		
2. Composite Score	GL_COMP		
3. Percentile Rank	GL_PERCENT		
4. Confidence Interval	GL_CONFINT	--	GL_CONFINT_HIGH

**Baby hug Follow-up Study (BHFS)
WPPSI FORM**

Form 024
Revision 3

Tue Sep 22 10:31:37 EDT 2015

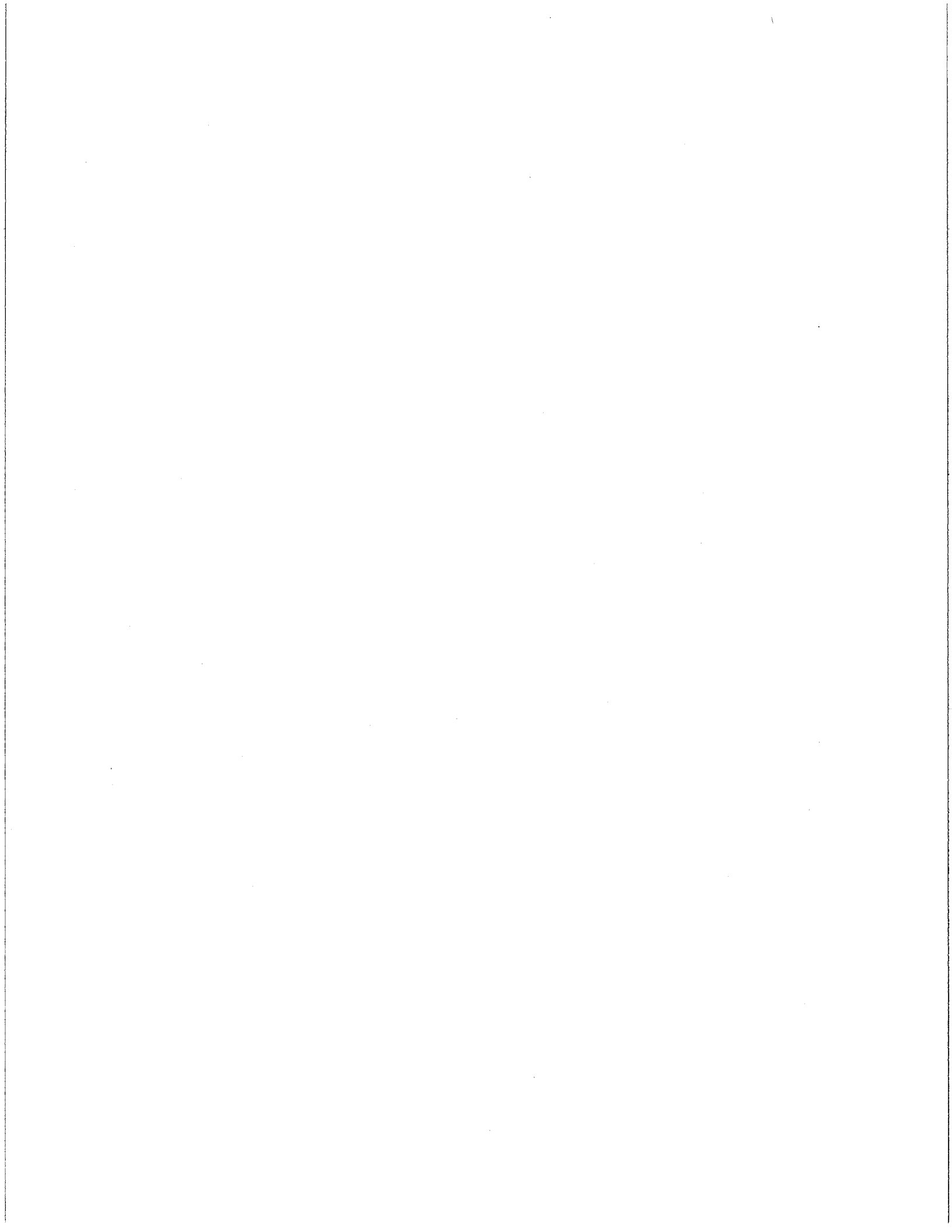
Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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Part III: COORDINATION

1. Checked for completeness and accuracy:

- A. Coordinator Certification number:
- B. Signature
- C. Neuropsychologist Name:
- D. General Comments

CERT_NO
CERT_SIG
NEURO_CET_NO
GEN_CMNT



Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

Form 025
Revision 1

Tue Sep 22 10:32:16 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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- 5. Admission Date
- 6. Discharge Date

ADM_DT
DISCH_DT

PART VIII: OUTCOMES

- 1. Significant new disability
- 2. Persistent new disability
- 3. Permanent new disability
- 4. Death
 - A. Date of Death
 - B. Location

SNEWDISA
PNEWDISA
PERMDISA
DEATH
DEATH_DT
DTH_LOC

PART IX: COORDINATION

- 1. Checked for completeness and accuracy:
 - A. Certification number
 - B. Signature:
 - C. General Comments:

CERT_NO
CERT_SIG
GEN_CMNT

Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

Form 025
Revision 1

Tue Sep 22 10:32:16 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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PART VI: REPORTABLE TREATMENTS

1. Answer each item

A. Transfusion

TRANSFUS

1. If yes, complete a. - d. Otherwise, skip to B.

a. Transfusion Type

TR_TYPE

b. Volume, answer b 1 or 2.

1. Whole Blood

TRVOLWBL

OR

2. Packed Red Cells

TRVOLPR2

c. Start Date

TSTRT_DT

d. Stop Date

TSTOP_DT

B. Placement on chronic transfusion therapy

CHRTRAN

C. Splenectomy

SPLCTMY

D. Parenteral antibiotics

PAR_ANTI

E. Dialysis, limited course

DIALYS_L

PART VII: HOSPITALIZATION

1. Hospital Name:

HOSPNAME

2. Hospital City:

HOSPCITY

3. Hospital State:

HOSP_ST

4. Hospital Zip:

HOSP_ZIP

Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

Form 025
Revision 1

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Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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- H. Seizures
- I. Headache
- 5. Results of Imaging Tests

SEIZURE
HEADACHE

- A. MRI of brain
- B. CT scan of brain
- C. PET scan of brain
- D. MRA cerebral vasculature
- E. Transcranial Doppler
- F. Arteriogram

F50MRI
F50CTBR
F50PTBR
F50MRA
F50TCD
F50ARTGR

PART V: DIAGNOSIS/PROBLEM SEVERITY AND ATTRIBUTION

Complete PART V for each item in PART III checked YES.

	Diagnosis/Problem	Date of Onset	Number of Days	Severity	Attribution to Study Treatment	Diagnosis Unexpected
1	PROBLEM	ONSET_DT	NUMDAYS	SEVERITY	ATTR_TRT	DIAGUNXP

Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

Form 025
Revision 1

Tue Sep 22 10:32:16 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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- B. Spleen size below LCM during SAE
- C. Nadir hemoglobin (in gm/dl)
- D. Platelet count at time of nadir hemoglobin (in k/ul)

SPLNSIZE_DURING
SPLNHMGL
SPLPTCNT

If PART III, Item 1C is YES, answer 3.
Otherwise, skip to 4.

- 3. Prolonged Hospitalization
 - A. Reason.

LONGHOSP_SP

If PART III, Item 1D is YES, answer 4-5.
Otherwise, skip to PART V.

- 4. (Stroke or TIA) Findings of
 - A. Loss of consciousness
 - B. Change in mental status
 - C. Loss of or difficulty with speech or vocalization
 - D. Paralysis or weakness
 - E. Difficulty with swallowing
 - F. Difficulty with vision
 - G. Loss of balance or dizziness

LOS_CONS
CHG_MENT
SPEECH
PARALYS
DIFFSWAL
DIFF_SEE
BALANCE

Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)

Form 025
Revision 1

Tue Sep 22 10:32:16 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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PART III: SAE

1. Please indicate all diagnoses:

- A. Acute chest syndrome
- B. Splenic Sequestration Crisis
- C. Prolonged Hospitalization (greater than 7 days)
- D. Stroke or TIA
- E. Life Threatening Event
 - 1. Specify
- F. Death
- G. ICU Admission

HX_ACS
HXSPLSEQ
LONGHOSP
HX_STROKE_TIA
LIFE_THREAT_EVT
LIFE_THREAT_EVT_SP
HX_DEATH
ICU

PART IV: ADDITIONAL DIAGNOSIS INFORMATION

If PART III, Item 1A is YES, answer 1.
Otherwise, skip to 2.

1. Acute Chest Syndrome

- A. New Infiltrate
- B. O2% Saturation on Room Air at Presentation
- C. Oxygen Administered (in Liters)
- D. Mechanical Ventilation

ACSNINF
ACSSRAP
ACSOXADM
ACSMVENT

If PART III, Item 1B is YES, answer 2.
Otherwise, skip to 3.

2. Splenic Sequestration

- A. Spleen size below LCM prior to SAE

SPLNSIZE_PRIOR

**Baby hug Follow-up Study (BHFS)
SERIOUS ADVERSE EVENT (ACTIVE GROUP ONLY)**

Form 025
Revision 1

Tue Sep 22 10:32:16 EDT 2015

Subject: SUBJECT_ID	Letter Code: LETTER_CD	Visit: VISIT_NBR
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1. Report Date: VISIT_DT

PART II: EVENT PERIOD

1. Date of Event

A. Event Start Date

START_DT

B. Event Ending Date

E_END_DT

2. Qualifying Procedure (Event must have occurred during the 5 days following a 24 month assessment procedure.)

Please note all that apply:

A. DTPA/GFR

DTPA_DT

or

DTPA_NA

B. Liver/Spleen Scan

LIVER_SPLEEN_DT

or

LIVER_SPLEEN_NA

C. Abdominal
Sonogram

ABD_SONO_DT

or

ABD_SONO_NA

D. WPPSI

WPPSI_DT

or

WPPSI_NA

E. Blood Specimens

BLOOD_SPEC_DT

or

BLOOD_SPEC_NA

**Baby hug Follow-up Study (BHFS)
ST. JUDE TRANSMITTAL FORM**

Form 101
Revision 3

Tue Sep 22 10:43:56 EDT 2015

1. Visit Date: VISIT_DT

The original printed transmittal form should accompany the specimen(s) to the Core Laboratory. Send the specimen(s) by Federal Express on the day of collection. For HJB and/or VDJ specimens, *place a cold (not frozen) gel pack above and below the styrofoam package*. Fax a copy of this transmittal list with the Federal Express tracking number to Core Laboratory. **Use one transmittal form per patient.**

*For Cystatin C specimens, follow preparation instructions in the MOO (Chapter 4) and ship frozen (separate from HJB and VDJ samples). If unable to spin red tops, ship Cystatin C priority overnight with cold gel pack as indicated for HJB and VDJ.

Clinical Center:	SITE_ID	Date Shipped:	VISIT_DT
Specimen Type	Label Number	Date Collected	
Howell-Jolly Bodies	BODIES_LABEL	BODIES_DT	
VDJ	VDJ_LABEL	VDJ_DT	
Cystatin C*	CYSTATIN_LABEL	CYSTATIN_DT	
Comments:	COMMENTS		

Send Specimen(s) and transmittal forms to:

Thad Howard
Baylor College of Medicine at Texas Children's Hospital
Ware lab
1102 Bates Feigin Research Bldg. Room 1070.01
Houston, TX 77030

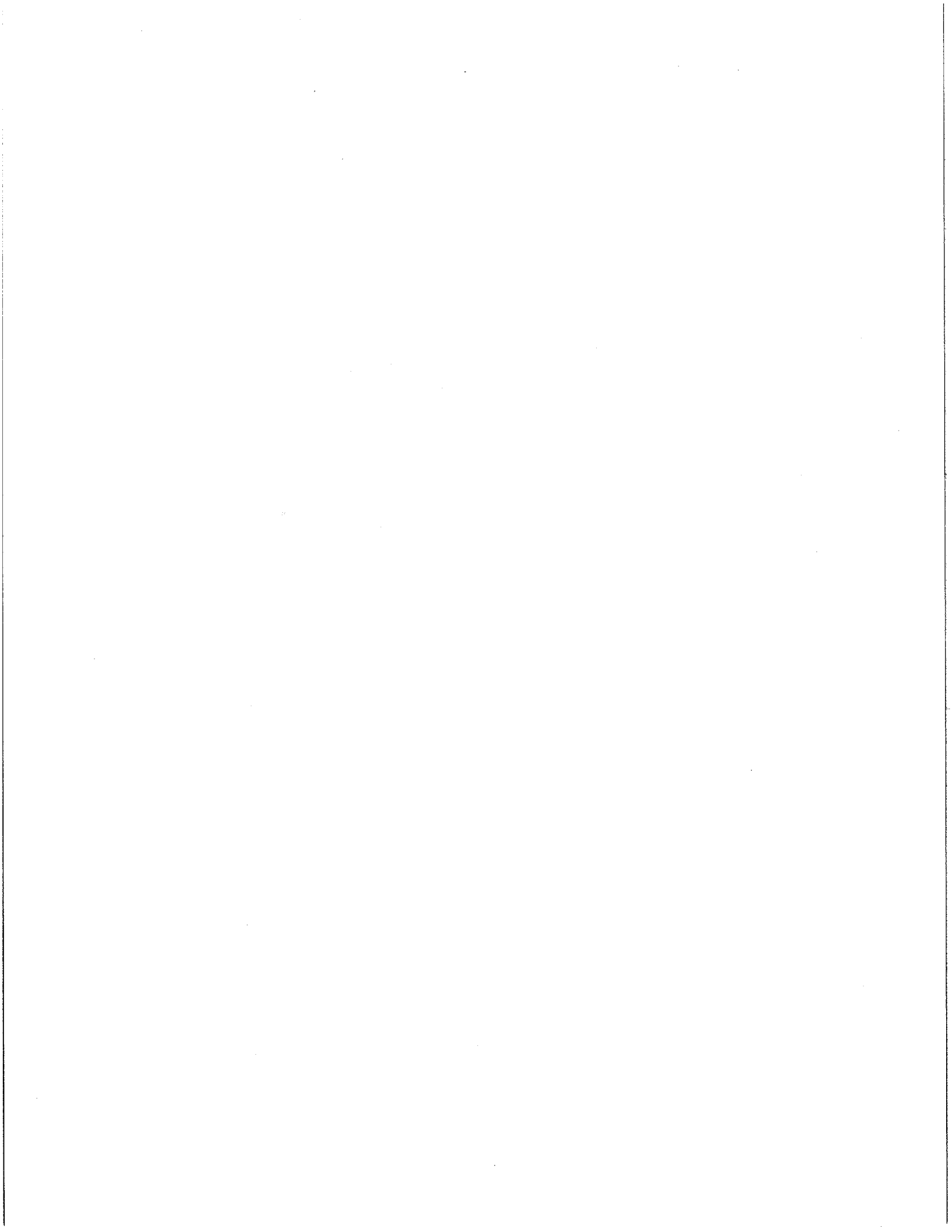
Fax form with Federal Express tracking number to Thad Howard, FAX No. 832-825-4846.

Clinical Center staff member completing form and verifying contents of shipment:

Name: Certification Number:

Federal Express Tracking Number:

TRACK_NUM



BABY HUG FOLLOW-UP STUDY
STEM CELL TRANSPLANT REPORT

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: 2. Current Clinic:
3. Patient's Letter Code:
4. Visit Date: - -
Month Day Year

PART II: TRANSPLANT INFORMATION

1. Date of Transplant: - -
Month Day Year

2. Location of Transplant Center

-
3. Reason for Transplant in Sickle Cell Disease
- | | |
|-------------------------------------|------|
| Stroke | (1) |
| Recurrent Acute Chest Syndrome | (2) |
| Recurrent Painful Episodes | (3) |
| Other Sickle Cell Related Cause | (4)* |
| Other NON Sickle Cell Related Cause | (5)* |

*a. Specify _____

ID Number Visit Seq

<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	-	<input type="text"/> <input type="text"/>
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4. Type of Graft:
- HLA Matched Sibling Bone Marrow (1)
 - HLA Matched Sibling Umbilical Cord Blood (2)
 - Matched Unrelated Donor (3)*
 - Matched Unrelated Umbilical Cord Blood (4)*
 - Haplo-Identical Parent* (5)*
- *a. For non-sibling donor, please indicate degree of matching:
- 6/6 (1)
 - 8/8 (2)
 - 5/6 5-6-7/8 (3)

PART III: TRANSPLANT COMPLICATIONS

1. What is the patient's current status with respect to their transplant? Answer all that apply.

- A. Death Date
- | | | | | | | | | | |
|-------|--|--|-----|--|------|--|--|--|--|
| | | | | | | | | | |
| Month | | | Day | | Year | | | | |
- B. Graft Rejection Date
- | | | | | | | | | | |
|-------|--|--|-----|--|------|--|--|--|--|
| | | | | | | | | | |
| Month | | | Day | | Year | | | | |
- C. Stable Mixed Chimerism
- | | | | | | | | | | |
|-------|--|--|-----|--|------|--|--|--|--|
| | | | | | | | | | |
| Month | | | Day | | Year | | | | |
- D. Cured of Sickle Cell Disease Date
- | | | | | | | | | | |
|-------|--|--|-----|--|------|--|--|--|--|
| | | | | | | | | | |
| Month | | | Day | | Year | | | | |
- E. Other (1)
- i. If other, please specify:
-
- ii. Date:
- | | | | | | | | | | |
|-------|--|--|-----|--|------|--|--|--|--|
| | | | | | | | | | |
| Month | | | Day | | Year | | | | |

^ COMPLETE FORM 25 – SERIOUS ADVERSE EVENT

ID Number	Visit	Seq

PART IV: COORDINATOR

1. Checked for completeness and accuracy:

A. Certification number:

--	--

 -

--	--

B. Signature: _____

C. General Comments: _____

ID Number	Visit	Seq									
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BABY HUG FU STUDY

VINELAND SUMMARY

PART I: IDENTIFYING INFORMATION

1. Patient's ID Number: 2. Current Clinic:
3. Patient's Letter Code:
4. Testing Date: - -
Month Day Year

PART II: CAREGIVER CODES:

1. Chronological Age:
Years Months Days

2. Caregiver's Relationship to Child:
- | | |
|---------------|-----|
| Mother | (1) |
| Father | (2) |
| Grandparent | (3) |
| Aunt or Uncle | (4) |
| Foster Parent | (5) |
| Other | (6) |

PART III: COMMUNICATIONS DOMAIN

1. Starting Row
2. Ending Row
3. Raw Domain Score
4. Standard Score
5. 95% Conf. Level
6. Percentile Rank

PART IV: DAILY LIVING SKILLS DOMAIN

1. Starting Row
2. Ending Row
3. Raw Domain Score
4. Standard Score
5. 95% Conf. Level
6. Percentile Rank

PART V: SOCIALIZATION DOMAIN

1. Starting Row
2. Ending Row
3. Raw Domain Score
4. Standard Score
5. 95% Conf. Level
6. Percentile Rank

PART VI: MOTOR SKILLS N/D

If not done, skip to Part VII

- 1. Starting Row
- 2. Ending Row
- 3. Raw Domain Score
- 4. Standard Score
- 5. 95% Conf. Level
- 6. Percentile Rank

PART VII: COORDINATION

1. Checked for completeness and accuracy:

a. Certification number:

--	--

 -

--	--

b. Signature: _____

c. General Comments:

ID Number

--	--	--	--

Visit Seq

--	--	--

 -

--	--

PART III: RESULTS

- 1. Splenic uptake (answer only one):
 - A. Normal (1)
 - B. Present, but decreased (2)
 - C. Absent (3)
 - *D. If decreased,
 - 1. < 50% decreased (1)
 - 2. > 50% decreased (2)

PART IV: COORDINATION

- 1. Checked for completeness and accuracy:

- A. Certification number:

--	--

 -

--	--
- B. Signature: _____
- C. General Comments: _____

ID Number	Visit	Seq									
<table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>					<table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				<table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>		

BABY HUG FOLLOW-UP STUDY

ABDOMINAL SONOGRAM (ULTRASOUND) CENTRAL READING

PART I: IDENTIFYING INFORMATION

- 1. Patient's ID Number:
- 2. Current Clinic:
- 3. Patient's Letter Code:
- 4. Procedure Date: - -
 Month Day Year

PART II: EQUIPMENT

- 1. Reader's Last Name:
- 2. Reader Signature: _____

- 3. Reader Number:
- 4. Date of Reading: - -
 Month Day Year
- 5. Film Label Number:
- 6. Current Status of this Reading:

- Quality adequate and reading complete (1)
- Returned for reprocessing (2)*
- Quality inadequate for reading after reprocessing (final) (3)**

*A. If returned for reprocessing, explain: _____

**B. If inadequate, explain: _____

If 2 or 3, Skip to Part IV.

PART III: RESULTS

	Present	Absent	N/A
1. Gallbladder	(1)	(2)	(3)

If Absent or N/A , Skip to Item 2.

A. If Present

Normal thin wall	(1)
Thick walled or edema	(2)
Not able to assess	(3)

	Minimal	Moderate	Marked	N/D
B. Color Doppler Vascularity	(1)	(2)	(3)	(4)

C. If gallbladder present, answer C1 or C2:

1. Number of Stones

OR

2. Multiple stones not countable Yes
(1)

D. Largest stone mm N/A
(1)

	Yes	No	N/A
E. Stones Freely Mobile?	(1)	(2)	(3)

	Dilated	Normal	N/A
F. Dilation			
1. Common bile duct	(1)	(2)	(3)
2. Pancreatic duct	(1)	(2)	(3)
3. Intrahepatic ducts	(1)	(2)	(3)

	Present	Absent	N/A
G. Sludge	(1)	(2)	(3)
H. Pericholecystic fluid	(1)	(2)	(3)

ID Number	Visit	-	Seq
<input style="width: 30px; height: 15px;" type="text"/> <input style="width: 30px; height: 15px;" type="text"/> <input style="width: 30px; height: 15px;" type="text"/> <input style="width: 30px; height: 15px;" type="text"/>	<input style="width: 30px; height: 15px;" type="text"/> <input style="width: 30px; height: 15px;" type="text"/> <input style="width: 30px; height: 15px;" type="text"/>	-	<input style="width: 30px; height: 15px;" type="text"/> <input style="width: 30px; height: 15px;" type="text"/>

2. Spleen Present (1) Absent (2) N/A (3)

If Absent or N/A, Skip to Item 3.

A. Accessory spleen(s) (1) (2) (3)

B. Cephalocaudad length [][] . [] cm

C. Transverse [][] . [] cm

D. Anterior – Posterior [][] . [] cm

E. Estimated total spleen volume [][][] cu cm (1) N/D

F. Homogeneity
 Homogeneous (1)
 Inhomogeneous (2)*
 N/A (3)

*1. If inhomogeneous, explain: _____

3. Right Kidney Present (1) Absent (2) N/A (3)

If Absent, Skip to Item 4.

A. Estimated volume [][][] cu cm

B. Renal parenchyma Normal (1) Abnormal (2)* N/A (3)

*1. If abnormal, explain: _____

C. Echogenicity (1) (2)* (3)

*1. If abnormal, explain: _____

ID Number Visit Seq

[][][] - [][] - [][]

	Present	Absent	N/A
4. Left Kidney	(1)	(2)	(3)

If Absent, Skip to Item 5.

A. Estimated volume cu cm

	Normal	Abnormal	N/A
B. Renal parenchyma	(1)	(2)*	(3)

*1. If abnormal, explain: _____

	(1)	(2)*	(3)
C. Echogenicity			

*1. If abnormal, explain: _____

	Yes	No	N/A
5. Liver enlarged	(1)	(2)	(3)

	(1)*	(2)	(3)
6. Any other abnormalities			

*A. If yes, explain: _____

PART IV: COORDINATION

1. Checked for completeness and accuracy:

A. Certification number: -

B. Signature: _____

C. General Comments: _____

ID Number	Visit	Seq
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>