

QUEJA FORMAL / FORMAL COMPLAINT

Padres / Parents: Mercedes Cepeda López y David López

Paciente / Patient: Snyder López – Fecha de nacimiento / Date of Birth: 04 de junio de 2011

Documento en cuestión / Document in Question: "Conditions of Admission" – 29 de abril de 2021 / April 29, 2021 (CHLA)

VERSIÓN EN ESPAÑOL

HECHOS Y NEGLIGENCIAS DETECTADAS:

1. Uso indebido de consentimiento general para justificar procedimientos experimentales sin consentimiento específico.
2. Cambio de protocolos de estándar a alto riesgo sin autorización de los padres.
3. Encubrimiento de información médica y riesgos reales.
4. Violaciones a HIPAA y 45 CFR 46 (Common Rule), además de posible abuso financiero.
5. Posible experimentación encubierta (ej. códigos QC o QCY) sin consentimiento informado.

SOLICITUD:

- Entrega inmediata de los expedientes médicos completos de Snyder López.
- Apertura de investigación formal sobre cambios de protocolo y uso indebido de consentimientos generales.
- Reconocimiento de violaciones a los derechos de los padres y del paciente.

ENGLISH VERSION

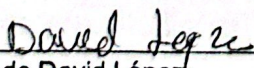
FACTS AND NEGLIGENCE IDENTIFIED:

1. Improper use of general consent to justify experimental procedures without specific informed consent.
2. Protocol changes from standard to high-risk without parental authorization.
3. Concealment of medical information and real risks.
4. Violations of HIPAA and 45 CFR 46 (Common Rule), plus possible financial abuse.
5. Possible hidden experimentation (e.g., codes QC or QCY) without informed consent.

REQUEST:

- Immediate delivery of Snyder López's complete and unaltered medical records.
- Formal investigation into protocol changes and misuse of general consent.
- Acknowledgment of violations of parental rights and Snyder's right to transparent, ethical, and lawful care.


Firma de Mercedes Cepeda López


Firma de David López

ANEXOS Y REFERENCIAS

1. Formularios de consentimiento general en hospitales de California:

Los formularios de ingreso autorizan atención básica, procedimientos médicos comunes y participación de estudiantes, pero no sustituyen consentimientos específicos.

Fuente: Los Angeles County General Consent Form (lacounty.gov)

2. Derechos del paciente en CHLA:

Los pacientes y padres deben recibir información completa sobre los riesgos y alternativas de cualquier tratamiento, y tienen derecho a negarse a participar en investigación.

Fuente: Children's Hospital Los Angeles – Patient Rights (chla.org)

3. Formularios de consentimiento para investigación clínica:

Para ensayos clínicos, CHLA requiere formularios separados con secciones detalladas de riesgos, beneficios y autorizaciones firmadas por padres/tutores.

Fuente: CHLA IRB Consent Form Checklist (chla.org)

ENGLISH VERSION

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Firma de Mercedes Capriles López

Firma de David López

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Paciente / Patient: Snyder López – Fecha de nacimiento / Date of Birth: 04 de junio de 2011

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Firma de Mercedes Cepeda López

Firma David
este año

→

David López
Firma de David López

Padres / Parents: Mercedes Gopetz López y David López
Patient / Patient: Snyder López - Fecha de nacimiento / Date of Birth: 04 de junio de 2011
Documento en cuestión / Document in Question: "Conditions of Admission" - 23 de abril de 2021
April 23, 2021 (CHLA)

VERSIÓN EN ESPAÑOL

HECHOS Y NEGLIGENCIAS DETECTADAS:

1. Uso indebido de consentimiento general para justificar procedimientos experimentales sin consentimiento específico.
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Mercedes Gopetz López
Firma de Mercedes Gopetz López

Información del documento

Tipo de resultado: Pre-Surgical Note (24hrs)
Fecha del resultado: Abril 29, 2021, 10:45 a.m.
Estado de resultados: authenticated
Realizado por: Young Chang
Verificado por: Young Chang
Modificado por: Young Chang

24 hour update

Paciente: SNYDER LOPEZ Fecha de nacimiento: Junio 04, 2011

Pre-Surgical Note (24 hrs)

I have reviewed the History and Physical, examined the patient, concur with the findings, and there are no interval changes.

I confirmed the scheduled procedure and verified the MD certification regarding ongoing treatment with the patient/patient's legal representative. The patient/patient's legal representative is aware that I will be performing the procedure.

Result Type: Hematology-Oncology OP MD Note
Result Date: April 01, 2021 11:13
Result Status: Auth (Verified)
Result Title: Office Visit Note
Performed By: Doyle (NP) ,Melissa on April 01, 2021 11:50
Verified By: Doyle (NP) ,Melissa on April 01, 2021 11:50
Encounter info: 2108800584, HEMATOLOGY/ONCOLOGY, Series Calendar Month, 04/01/2021 -

* Final Report *

Date of Service

Date of Service: April 01,2021

Referring Provider: Dr. Balette

Accompanied by

Problem List

Current

ALL (acute)
Autistic beh

Accompanied by: Father

Chief Complaint

follow up

Here for Maint 3C

History of Present Illness

Snyder has been doing very well this past month. He is camping with his family this week, camp in today for appt. In great spirits. Has a healing bug bite ti right lateral ankle region, also injured left middle finger yesterday when playing football but overall doing great. No concerns from father today

Treatment Hx/Disease Hx

Snyder Lopez is a 9 year-old boy w/ Autisim presenting with left leg pain since 11/18/19, radiating up body, fevers, vomiting blood, and nose bleeds, with labs concerning for leukemia.

4 years ago w/ frequent nosebleeds (20-30 minutes). Seen by A/I, Hematology, Oncology, ENT, and everything was normal. Last saw Hematology in 2018.

In the last month, has begun having left arm, left leg, and back pain that comes and goes. Sometimes they are disabling and prevents him from being able to walk and missing school x 1 week. Responds well to ibuprofen. Has also had night sweats, weight loss, and fevers.

Went to Mexico and went to pediatrician for symptoms. Labs done, and are reported normal. CBC was normal about 2-3 weeks ago. In the last week has had a productive cough, fever and abdominal pain. Has had a prolonged nosebleed x 40 minutes followed by bloody vomiting with clots

Has seen A/I for allergies, Endocrinology for hyperglycemia, and Hematology for nosebleeds. Has had multiple blood tests, and says that multiple tests are abnormal (calcium, phosphorus, thyroid). Upon review, Calcium and phosphorous is slightly elevated. TSH is normal. FT4 slightly above ULN.

He was diagnosed with SR ALL, CNS negative; started chemo on 12/26/19

Durin admission there was initial concern for an IVC thrombus on his initial echo so he was started on enoxaparin. IVC US did not show a thrombus and repeat echo did not show a thrombus with the initial echo then thought to be more consistent with artifact.

ID standpoint - he received 2 days of meropenem on admission for fevers (12/24-12/26), then transitioned to cefepime x1 day, he was then transitioned to complete a 7 day course of CTX for pneumonia on admission (12/28-12/31).

Hyperdiploid but not 4+10

TPMT 1/1

NUDT double heterozygote with intermediate activity

01/02/20	Induction	Day 8	10.1	42	2.59	1.32	Blasts 1.7%, 2.7% by Flow
01/09/20		Day 15	7.6	38	0.73	0.57	16.4% NRBC's 0 0 blasts by morphology
01/16/20		Day 22	10.0	142	0.72	0.63	c/o testes pain
01/20/20		Day 26					Admitted with mouthsores
01/27/20	Induction	Day 29					MRD 0.037% * Final Report
01/31/20	Consolidation	Day 1					
02/01/20		Day 2					Admitted with HA (post LP)
02/14/20	Consolidation	Day 15	10.2	289	3.92	3.01	ALT 888/ AST 593 Vcr/PEG

Encounter for
Need for pr

Chronic

Anemia
Leukopenia
Bleeding
Acute lymph
Need for pr
Autistic beh
ALL (acute l
Ankle pain,
Abnormal tr
Acute hyper
Encounter for

Past Medical

Encounter for
Acute hyper
Abnormal tr
Ankle pain,
ALL (acute l
Autistic beh
Need for pr
Acute lymph
Bleeding
Leukopenia
Anemia

Procedure/Su

04/10/2020 Bc
01/27/2020 Bc
12/26/2019 Bc

Medications

acyclovir 400
Bactrim 400 m
BIDSaSu, 12
fluticasone 50
refills
mercaptopurin
QHS
methotrexate :
QWeekly F
MiraLax oral p
refills
montelukast 5
QHS, 11 refills
sennosides-dc
QHS, PRN, 12
Transderm-So
release, See li
triamcinolone
BID, PRN, 1 re

Allergies

Tegaderm (Ra
Cat Hair
Olive
Seafood
Sesame Seed
pegaspargase
vancomycin (F

Social Histor

02/21/20 Day 22 9.2 216 3.94 2.03

03/05/20 11.9 484 7.37 3.05 ALT 577/ AST 341

03/06/20 Consol 29

03/13/20 Consol 36 10.2 253 3.30 2.33

03/19/20 Consol 43 8.1 98 2.10 1.39

04/02/20 Due IM #1 9.8 665 1.57 0.40

04/23/20 IM #1 Day 15 11.2 208 4.30 2.51

05/07/20 IM #1 Day 29 11.0 238 2.73 1.98

06/19/20 DI Day 1 12.9 290 3.18 2.13

06/22/20 Erwinia M_W_F x 6

06/26/20 DI Day 8 13.3 286 8.77 8.08

07/02/20 DI Day 15 12.1 159 2.52 1.53 VCr/ ADR

07/09/20 DI Day 22 13.0 173 2.73 1.94 hyperglycemia

07/20/20 DI Day 29

admitted with fever, perianal abscess

07/30/20 DI Day 43 Vcr only

08/06/20 DI Day 50 8.3 188 0.64 0.12 VCR/ start Erwinia

08/10-15 Admitted with neutropenia and clinical sepsis, constipation

08/21/20 M1A 9.4 302 3.45 2.06(m) 75 (80%) 25(100%) 7.5 divided

09/04/20 M1 day 15 8.4 70 3.50 2.64 50 (55%) 25 (100%)

09/18/20 M 1B 8.5 183 2.10 0.97 50 (55%) 25 (100%) Port removal 9/21/20

10/15/20 M1C 11.5 321 3.50 2.31 50 (55%) 25 (100%)

11/12/20 M2A 11.5 300 3.37 2.01 50x5, 75x2 25 (100%) Increase 6MP

12/10/20 M2B 11.7 310 3.10 2.02 50x5, 75x2 25 (100%)

01/07/21 M2C 12.3 315 3.71 2.67 75 25

02/04/21 M3A 11.7 322 2.63 1.90 75 25

03/04/21 M3B 11.5 322 2.85 1.85 75 25

04/01/21 M3C 11.6 338 2.63 1.87 75 30 Increase MTX

EOT: 4/10/2023 [1]

Review of Systems

Constitutional: Denies fever, Denies chills, Denies fatigue.

Eye: Denies icterus, Denies blurred vision.

Ear: Denies pain, Denies hearing change.

Nose: Denies congestion, Denies discharge.

Throat: Denies sore throat, Denies oral lesion.

Respiratory: Denies cough, Denies shortness of breath.

Cardiovascular: Denies chest pain, Denies palpitations.

Gastrointestinal: Denies abdominal pain, Denies nausea, Denies vomiting, Denies diarrhea, Denies constipation.

Genitourinary: Denies urinary frequency, Denies hematuria.

Musculoskeletal: Denies joint pain, Denies muscle pain.

Hematologic/Lymphatic: Denies bruising, Denies bleeding gums, Denies epistaxis.

Skin: Denies jaundice, Denies rash.
Neurologic: Denies headache.

Never smoked

Physical Exam

Vitals & Measurements

T: 37.3 TMAX: 37.3 HR: 84 bpm BP: 111/62 (111-111/62-62) RR: 24

Parameter

Measurement

Date/Time

Z-Score

Med Calc Weight:

52.3 kg

(04/01/21 10:29)

>97%ile (Z-score=2.2)

Height:

131.2 cm

(04/01/21 10:29)

16%ile (Z-score=-1.0)

BMI:

30.38kg/m2

(04/01/21 10:29)

>97%ile (Z-score=2.5)

BSA:

1.38 m2

(04/01/21 10:29)

Physical Exam

General Appearance: Awake, alert, in NAD

HEENT: MMM, no oral lesions

Neck: supple, non-tender

Respiratory: respirations unlabored, symmetric chest rise

Chest: symmetric, non-tender

Cardiovascular: regular rate, distal pulses normal

Abdomen: Soft, NT, ND

GU: deferred

Extremities: WWP, no edema.

Neurological: CN II-XII intact, moving all extremities symmetrically

Skin: No rash, no other lesions

Musculoskeletal: MAEW

Assessment & Plan

9 y/o boy with Autism and newly diagnosed SR ALL, CNS negative. EOI MRD 0.037%, upstaged to HR protocol, EOC MRD negative. Being treated on CHLA HR protocol, now in Maintenance

Plan

Heme/Onc (3C)

Administer Vcr today

Start Dex pulse today x 5 days

6MP 75 mg qhs

INCREASE Methotrexate 30 mg po qweek, skip on LP day

ID

Continue Bactrim

Continue Acyclovir - 2 episodes, continue ppx throughout maintenance

Derm

Continue Nystatin to buttocks prn

Apply triamcinalone cream to rash on scalp

Allergies:

Had extensive allergy panel

Allergy clinic appt r/s, pt was inpatient at prev scheduled appt

Plan

RTC in 4 weeks for CBC/diff,chem 14 for M4A, VCR

In 4 weeks for LP with IT Mtx under GA

Patient seen by Melissa Doyle as the rendering provider under the supervision of Dr Paul Gaynon as the attending physician.

[2]

Patient Instructions

Prolonged Services

Attending Attestation

Send To

[1] Leukemia/Lymphoma - Maintenance chemo; Doyle (NP) ,Melissa 03/04/2021 12:00 PST

[2] Leukemia/Lymphoma - Maintenance chemo; Doyle (NP) ,Melissa 03/04/2021 12:00 PST

Signature Line

Author(s): Doyle (NP) ,Melissa Nurse Practitioner - Pediatric Hematol/Oncol

Lab Results
04/01/21 11:

\ 11.6 /

%Band
0.0

2.63 ----- 3

/ 36.7 \

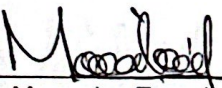
QUEJA FORMAL / FORMAL COMPLAINT

Mercedes Zepeda López & David López
Padres de Snyder López (DOB: June 4, 2011)

To: Office for Human Research Protections (OHRP), HHS

Subject: Formal Complaint – Violation of Federal Research Protections at CHLA

We respectfully submit this complaint concerning violations of federal research protections. Our son was subjected to hidden experimentation under the "Conditions of Admission" (April 29, 2021) without parental consent. This violates 45 CFR 46 – Common Rule, Subpart D. We request OHRP to investigate CHLA's compliance and impose corrective measures.


Firma de Mercedes Zepeda López


Firma de David López

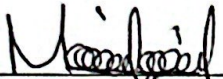
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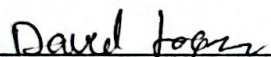
Mercedes Zepeda López & David López
Padres de Snyder López (nacido el 4 de junio de 2011)

A: Office for Human Research Protections (OHRP), HHS

Asunto: Queja formal – Violación de protecciones federales de investigación en CHLA

Presentamos esta queja respecto a violaciones de protecciones federales de investigación. Nuestro hijo fue sometido a experimentación encubierta bajo el documento "Conditions of Admission" (29 de abril de 2021) sin consentimiento parental. Esto viola la regulación 45 CFR 46 – Common Rule, Subparte D. Solicitamos al OHRP investigar el cumplimiento de CHLA e imponer medidas correctivas.


Firma de Mercedes Zepeda López


Firma de David López