



Welcome to the 2025 AXYS Community Conference!





International Scientific Committee

Alberto Ferlin, Italy
Claus Gravholt, Denmark
Anders Juul, Denmark
Armin Raznahan, USA
Anne Skakkebæk, Denmark

Hanna Swaab, The Netherlands Nicole Tartaglia, USA Sophie van Rijn, The Netherlands Joachim Wistuba, Germany



"A LIFELONG JOURNEY: NEW ANSWERS TO OLD QUESTIONS"

International Scientific Committee

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ACRC AXYS CLINIC AND RESEARCH CONSORTIUM Established in 2015

Share Information

Collaboration

ACRC GOALS

Development & Participation in Research

Education though Consensus-based Recommendations



ACRC Clinic Locations Multidisciplinary and Single Specialty Clinics



ACRC Activities and Results



Meetings with ACRC Members



Support of Research Projects



Support of Consensus Documents



ACRC Activities Current Efforts



Meetings with ACRC Members



Support of Research Projects, like GALAXY

GALAXY: Longitudinal collection of clinical and self-reported data to improve health outcomes



Support of Consensus Documents

Consensus statement on hypogonadism, fertility, and neurocognition: In process



Klinefelter Syndrome Program







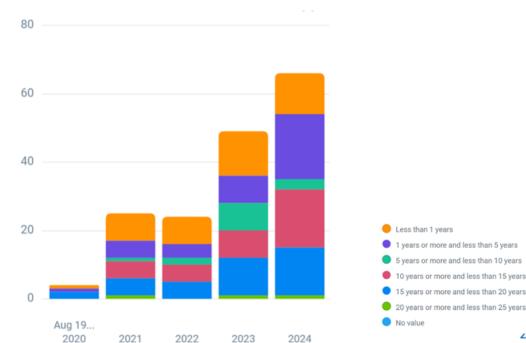


Clinical Program

- Team
 - Coordinator: Danielle Lee
 - **Endocrinology: Courtney Finlayson**
 - Genetic Counseling: Allison Weisman, Beth Leeth
 - Urology: Emilie Johnson, James Rague, Robert Brannigan (NW)
 - Psychology: Jackie Papadakis, Zach Huit
 - Neuropsychology
 - Developmental Pediatrics
- Monthly multi-disciplinary clinic
 - Prenatal consultation
 - Early Infancy
 - Childhood every 1-2 years
 - Adolescence and young adults every 6-12 months

Lurie KS Program currently sees about 200 patients

Significant increase each year since 2020 Formal KS Program started in 2023





Research Program

- Research Team:
 - Clinical Team +
 - Sarayu Ratnam
 - Luke Lucchio
 - Genetic counseling graduate students: Abby Tubman, Sofia Marrufo Cedeno





Finding acceptance: How adolescents and young adults with Klinefelter Syndrome navigate identity, disclosure, and support Abigail Tubman¹ | Jaclyn L. Papadakis^{2,3} | Courtney Finlayson^{4,5} | Debra Duquette^{1,6} | Allison Goetsch Weisman^{4,5,7}

Ongoing Projects

- GALAXY Registry
- KidS Camp
 - September-December 2024
 - August-October 2025
- Industry Trial-Xyosted < 18 years
- Navigating Testosterone Therapy: A Resource for People with Klinefelter Syndrome

The CHOP
Klinefelter
and other X and Y
Variation Program



Klinefelter and Other X and Y Chromosome Variations Program







CLINICAL EXPERIENCE

Established in 2016

- About 30 new patients annually
- Follows about 300 patients
- About 60% of our patients are babies prenatally diagnosed
- We provide longitudinal follow up throughout childhood.





RESEARCH ACTIVITIES

Our own clinical projects

- CHOP redcap registry
- Review of our outcomes and prospective studies



Journal of Pediatric Urology (2023) 19, 586-595

Information needs and health status in adolescents and young adults with differences of sex development or sex chromosome aneuploidies



^aDivision of Adolescent Medicine, HUB, 3500 Civic Center Blvd., Children's Hospital of Philadelphia, Philadelphia, PA, 19104, USA

^bDepartment of Pediatrics, Perelman School of Medicine, University of Pennsylvania. Victoria A. Miller ^{a,b,*}, Christina Miller ^c, Shanlee M. Davis ^{d,e}, Natalie J. Nokoff ^{d,e}, Cindy Buchanan ^{d,e}, Elizabeth A. Friedrich ^a, Alexandra Carl ^{d,e}, Sophia Strine ^f, Maria G. Vogiatzi ^{b,f}



RESEARCH ACTIVITIES

Collaborations

- Part of GALAXY
- Other collaborations & grants

The Journal of Clinical Endocrinology & Metabolism, 2022, 107, e1850—e1859 https://doi.org/10.1210/clinem/dgac056 Advance access publication 01 February 2022 Clinical Research Article





Population-based Assessment of Cardiometabolicrelated Diagnoses in Youth With Klinefelter Syndrome: A PEDSnet Study

Shanlee M. Davis, 1,2,10 Natalie J. Noko Patricia Fechner, 5,10 Chijioke Ikomi, 6,10 Maria G. Vogiatzi, 10,10 and Amanda De

¹Department of Pediatrics, University of Colorado Scho ²eXtraOrdinarY Kids Clinic, Children's Hospital Colorado ³Adult & Child Consortium for Health Outcomes Rese Aurora, CO 80045, USA

⁴Department of Biostatistics and Informatics, Universite ⁵Department of Endocrinology, Seattle Children's Hospi ⁶Division of Endocrinology, Nemours Children's Health, ⁷Institute for Informatics, Washington University Schoo ⁸Center for Biobehavioral Health, Abigail Wexner Rese ⁹Division of Endocrinology, Nationwide Children's Hospi ¹⁰Department of Pediatrics, Children's Hospital of Phila ¹¹Merck and Company, Wales, PA 19454, USA

Correspondence: Shanlee Davis, 13123 E 16th Ave B265, Auro

Original Article

SDC

Neurodevelopmental and Mental Health Outcomes in a National Clinical Sample of Youth With Sex Chromosome Trisomies Compared With Matched Controls

Adriana Hall, MD*, Anna Furniss, MS[†], Nicole N. Tartaglia, MD, MS^{‡,§}, Jennifer Janusz, PhD^{‡,§}, Rebecca Wilson, PsyD^{‡,§}, Caitlin Middleton, PsyD^{‡,§}, Sydney Martin, MS, OTR/L, BCP[‡], Jacqueline Frazier, MA, SLP[‡], Michele Martinez-Chadrom, MA, SLP[‡], Jennifer Hansen-Moore, PhD^{II}, Chijioke Ikomi, MD[¶], Judith Ross, MD[¶], Maria G. Vogiaski, MD**, Leela Morrow, PsyD^{††,±‡}, Dimitri A. Christakis, MD, MPH^{§§,III}, Rachel E. Lean, PhD^{¶,¶}, Natalie Nokoff, MD, MS[§], Laura Pyle, PhD^{§,***}, Shanlee M. Davis, MD, PhD^{‡,§}



ACRC Overview

Geisinger

Matthew T. Oetjens, PhD
Department of Developmental Medicine
Assistant Professor
Geisinger College of Health Sciences

ACRC Research Overview

- Location: Rural Central Pennsylvania
- MyCode Community Health Initiative
 - 230,000+ participants with linked genetic data
 - Proteomic data collection in progress
- Enables population-based identification of individuals with sex chromosome variations (SCVs)
- Team members: Matthew Oetjens PhD, Brenda Finucane, MS, CGC, Makenzie Woltz, MS CGC

ACRC Research Overview

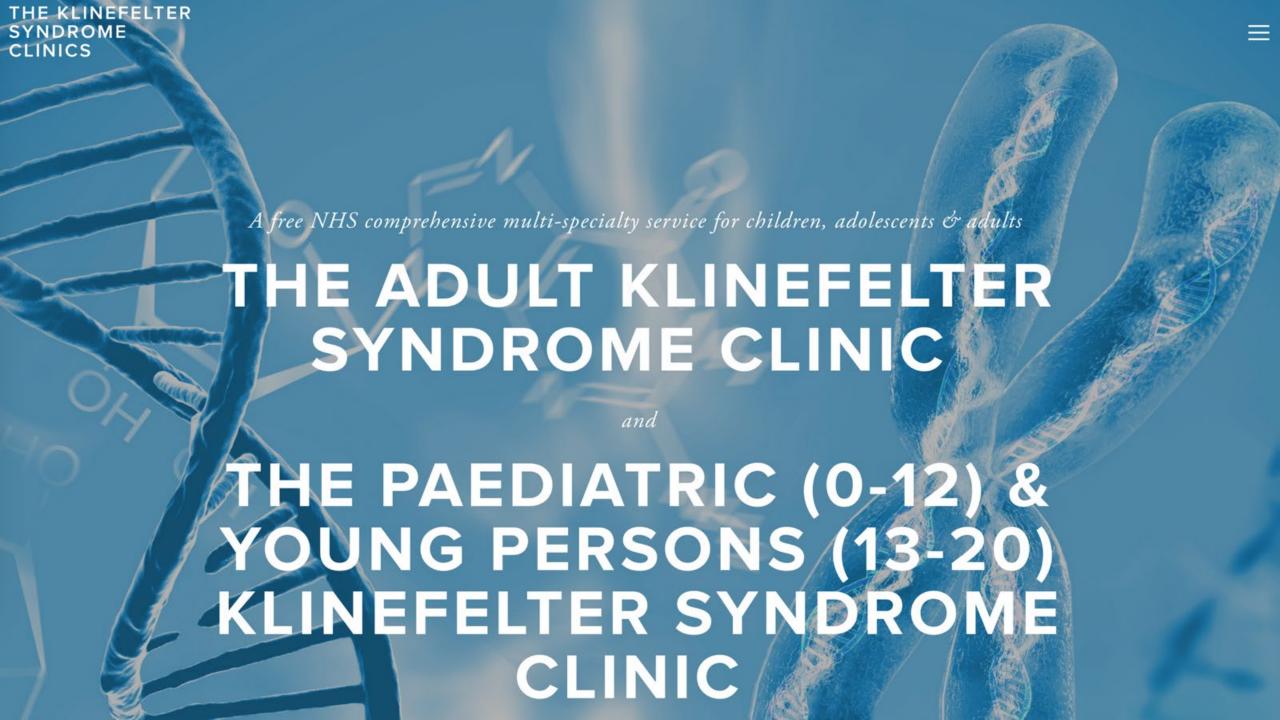
Current Research Focus

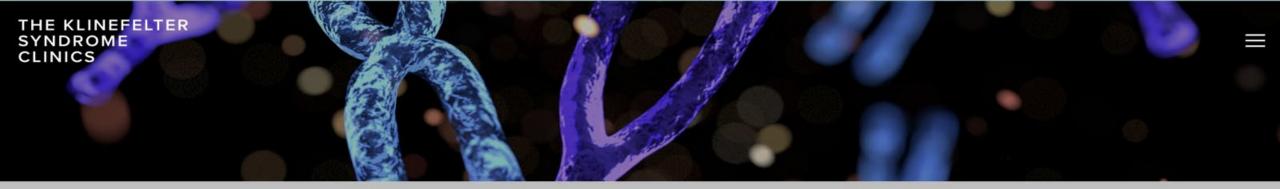
- Identifying disease risks associated with SCVs
- Risk modeling to improve patient outcomes
- Evaluating population screening for sex chromosome variations (most adults undiagnosed)

Impact Goals

- Improve gaps in health care of sex chromosome variations
- Personalize care through genomic and clinical
- Inform public health strategies for genetic conditions







The Klinefelter Syndrome Multi-Specialty Clinics London, UK:

One of the first in the UK to address the needs of patients diagnosed with Klinefelter (XXY) Syndrome from birth to old age.

Three types of free clinics:

- Adults (The Adult Klinefelter Syndrome Clinic)
- Young people aged 13-20 (The Klinefelter Syndrome for Young People)
- Children aged 0-12 (The Paediatric Klinefelter Syndrome)

Each clinic runs **four** times a year except the paediatric clinic which currently runs once a year, with plans to increase its frequency soon!

The Klinefelter Clinics Multi-Specialty Team:

Range of dedicated health professionals who are specialists in KS management, including:

- Urology
- Genetics
- Endocrinology
- Psychosexual
- Psychology
- Neurodisability
- Plastic Surgery
- Fertility and Embryology







Tet Yap - Lead & Urology Consultant (Adult & Young Person's Clinic)



Alessandra Cocca -**Paediatric** Endocrinology Consultant (Young Person's Clinic)



Leila Frodsham -**Psychosexual Medicine Con** sultant (Adult Clinic)



Jackie Porter - _ **Anaesthetistics Consultant (Adult** Clinic)



Karen Briggs -**Uro-Andrology** Nurse **Practitioner** (Adult & Young Person's Clinic)



Barbara McGowan -**Endocrinolog** y Consultant (Adult Clinic)



Paula Allchorne -**Nurse Practitioner** (Young Person's Clinic) and **Psychosexual Counsellor Trainee** (Adult Clinic)



Claire Harkin KSA Volunteer, CYP Psychotherapeutic Counsellor trainee (Paediatric Clinic)



Charlotte Tomlinson -Genetics Counsellor (Adult & Young Person's Clinic)



Paul Carroll -Consultant (Adult Clinic)



Davide Prezzi - Radiology Consultant (Adult & Young Person's Clinic)

Jennifer

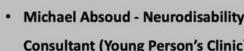
(Young

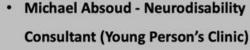
Clinic)

Person's



(Adult Clinic)





- Kirpal Sahotra Psychiatry Consultant
- Simon Filson Plastic Surgery Consultant
- · Niamh Foran Specialist Klinefelter **Pharmacist**





Yulia Kopeika -Reproductive Medicine Consultant (Adult Clinic)



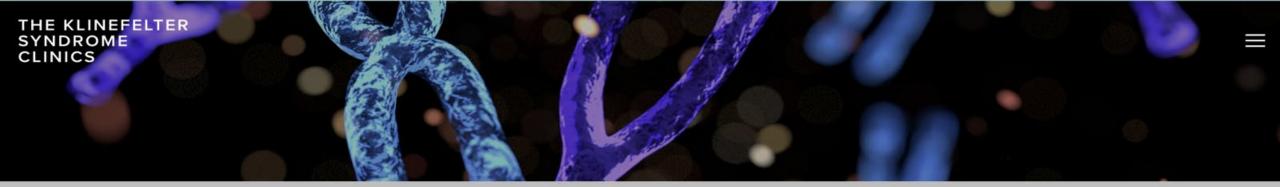
Shirif -Reproductive Medicine **Specialist** (Adult & Young Person's

What does the visit involve?

- One-stop clinic that covers all important aspects of KS.
- Specialists in genetics, endocrinology, urology, reproductive medicine, psychosexual medicine, radiology, adolescent psychology, educational psychology etc.
- Nurse counsellor present to address any other personal concerns a patient may have.
- Individualised management plan created for each patient based on priorities, given to patient and GP/referring clinician.
- Klinefelter Syndrome Association (KSA) may be present who may be able to give a
 personal view on living with KS.
- 2 to 2.5 hours in the hospital to allow all the tests and consults to be completed.
- Our young persons clinic provides access to the adult clinic once patients are over 21







Research and Development:

National KS RedCap database:

- Long term data on the natural history of KS is still lacking, especially regarding risk of thromboembolism, effects of Testosterone therapy, fertility outcomes and risk of osteoporosis, diabetes and cancers – all issues linked to KS patient care.
- Secured funding from the KSA
- Results of the study will be published in recognised journals.
- KS patients will not be identified in any publication.

National KS Biobank:

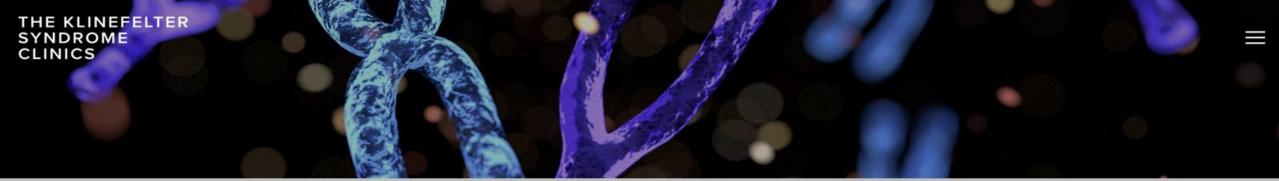
- Collects and stores cells and tissue in ways that is suitable for many different types of research.
- Helps us learn more about KS.
- Research to identify cell characteristics to be even more certain that a particular treatment will be effective.
- Observe effects of new drugs and tests before clinical trials begin with volunteer patients.

KS Passport:

- Comprehensive guide for individuals with KS.
- Developed with patients, doctors and allied health professionals dedicated to the care of patients with KS.
- Includes resources to share with GPs and employers.
- Can be used by patients and healthcare professionals.
- 6 monthly reviews and updates of content or whenever important KS findings are announced.







CONTACT US

If you have any questions or concerns about the **Klinefelter Syndrome Multi-Specialty Clinics**, please contact Karen Briggs, clinical nurse practitioner:

Email: karen.briggs@gstt.nhs.uk

• Telephone: 07717 346821

Monday to Friday, 9am to 5pm

KS Clinics website:

https://theklinefeltersyndromeclinic.com/about

KSA website:

https://www.ksa-uk.net/



The eXtraordinary Kids Clinic, est. 2007 Children's Hospital Colorado, Aurora/Denver University of Colorado School of Medicine



Multidisciplinary Evaluations (1-3 days):

- Developmental Pediatrics
- Genetic Counseling
- Endocrinology
- Psychology

- Neuropsychology
- Speech / Language
- Occupational Therapy
- Social Work





Since July 2020, we have seen >545 X&Y Patients

eXtraordinarY Kids Clinic: interdisciplinary team

Goal: to provide comprehensive interdisciplinary evaluations and treatment recommendations for children and adolescents with X and Y chromosome variations

Developmentalbehavioral pediatrics

Clinic director
Team leader
evaluation of:
• Physical features
• Medical problems
associated with SCA
Psychopharmacologic
medication
recommendations and

management

Child psychology

Evaluation of:

- Behavioral and Emotional functioning
- Cognitive functioning
 Social skills/autism
- spectrum disorders

 Adaptive functioning
 Home and school
 Behavioral strategies

Pediatric Neuropsychology

Evaluation of:

- Cognitive functioning
 Learning disabilities
- · ADHD
- · Executive functioning
- · Visual-spatial skills
- Memory functioning Educational recommendations

Speech-language therapy

Evaluation of:

- Understanding of language
- Verbal expression
- Speech production including apraxia
 Recommendations for therapy and school/ home strategies if needed

Occupational therapy

Evaluation of:

- Fine and gross motor skill
- Adaptive/daily living skills
- Sensory processing differences

Recommendations for therapy and school/ home strategies if needed

Pediatric Endocrinology

Evaluation/treatment of:

- Hypogonadism (Testosterone deficiency) in XXY, XXYY, XXXY, and XXXXY
- Endocrine risks (including type II diabetes, thyroid disorders)
- Overweight/obesity

Nursing

- Communication and coordination with families
- Support for medication management and refills

Social work

- Identification of community and government resources
- Assistance with transition planning
- Involvement in complex cases

Genetic counseling program:

Clinic coordination (intake and scheduling) Genetic counseling for cases ascertained through:

- Non-invasive prenatal testing (NiPT)
- · Prenatal CVS and amniocentesis
- · Postnatal diagnosis

Family support and strategies for thoughtful disclosure of diagnosis to affected child/adolescent Family planning for affected adults



Team formulation of diagnoses and treatment recommendations



Feedback session with family including discussion of concerns, team impressions, and recommendations, comprehensive written report

Psychopharmacological medication management:

- By DBPediatrics for treatment of: ADHD, anxiety, other behavioral and mood disorders
- · Nursing support

Testosterone therapy management:

- · By endocrinology
- Nursing support
- Joint appointment with DBPeds if needed





Infant developmental evaluations:

Developmental monitoring and evaluation for infants diagnosed in the prenatal or newborn period. Evaluation includes:

- Developmental—behavioral pediatrics
- Occupational therapy
- Speech therapy

Physical therapy

Research

- Neurodevelopmental phenotypes
- DNA repository
- · Genotype-phenotype studies
- Clinical trails

Education

- Continuing education presentations for professionals
- Trainees (residents, graduate students and fellows)
- Development of professional and training materials

Support and advocacy

- · Family-centered events and conferences
- Development of family support materials
- Collaboration with national advocacy organizations

- Research (studies, publications)
- Education/Teaching Providers and Trainees (clinical, research)
 - Educational Materials for Families



























Advocacy for patients and families Collaborations with AXYS, The XXYY Project, Living with XXY,

International groups











eXtraordinary Kids Clinic (www.extraordinarykidsclinic.org)

The NIMH Intramural Study on X and Y Chromosome Variations

Phase 1 (Dr. Jay Giedd): 1990 – 2010 | Phase 2 (Dr. Armin Raznahan): 2015 onwards -> over 250 families seen so far (XYY, XXY, XXX)



















Clinical team (above) + molecular biologists, neuroscientists, computational experts + collaborators

Our goal: To better understand X- and Y-chromosomes effects on neurodevelopment so we can better address families' questions and needs

The study: Families attend the NIH Clinical Center in Maryland, USA for a <u>2-day visit (flights and hotel covered)</u> including detailed autism, mental health, and cognitive assessments + brain scans and blood samples

A <u>detailed clinical report</u> (assessment and recommendations) for each family to have and use

Improved understanding of cognitive/behavioral impacts & underlying changes in the brain and genome

How do different X/Y variations impact mental health?

Do any of these impacts vary by age?

Which mental health symptoms most impact functioning? Can we use family data to better predict individual outcomes?

Which genes, cell types and brain regions should we focus on and when?





Male Reproductive Medicine Program For X and Y Variations

Hooman Sadri MD, PhD
Associate Professor of Urology and Regenerative Medicine





> Target Patients

- > IVF Couple (KS Embryo)
- Pregnant Mom (KS Fetus)
- Pediatrics
- Adults

PINDROLOGY SADRI FERTILITY LANGE OF THE PROPERTY OF THE PRO

Services

- Consultation
- Puberty Management with Preserving Fertility
- > Infertility Treatment
 - Medical Treatment
 - mTESE* (Fresh Sperm Retrieval with back up Donor Sperm)
- ➤ Long Term Testosterone Replacement Therapy (TRT)

Locations

- ➤ Six locations in 4 cities in North Carolina (Charlotte, Mooresville, Greensboro and Winston Salem)
- Telehealth (National and International)





- > Experimental Testicular Tissue Banking to Preserve Fertility Preservation
 - > Tests Biopsy Before Puberty if a clinical procedure under general anesthesia is required

Wake Forest* School of Medicine Institute for Regenerative Medicine

> Testicular Tissue Banking for Fertility Preservation in Boys and Men at Risk for Infertility



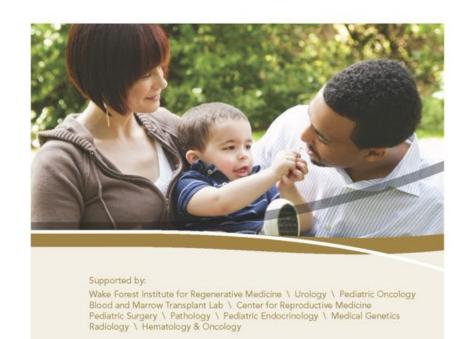


IRE 00021686

Institute for Regenerative Medicine

Testicular Tissue Banking

for Fertility Preservation in Boys and Men at Risk for Infertility











> Tests Biopsy Before Puberty if a clinical procedure under general anesthesia is required

> 3-Dimensional Human Testicular Organoid System (HTO) (Active Patent)

Application AU2019200730A events Priority claimed from US201161492151P 2019-02-04

Application filed by Inguran LLC

2019-02-04

Priority to AU2019200730A

2019-02-21

Publication of AU2019200730A1

2021-08-12

Application granted

2021-08-12

Publication of AU2019200730B2

Status

Active

2032-06-01

Anticipated expiration



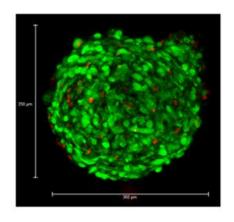
Testicular Tissue Banking for Fertility Preservation in Boys and Men at Risk for Infertility



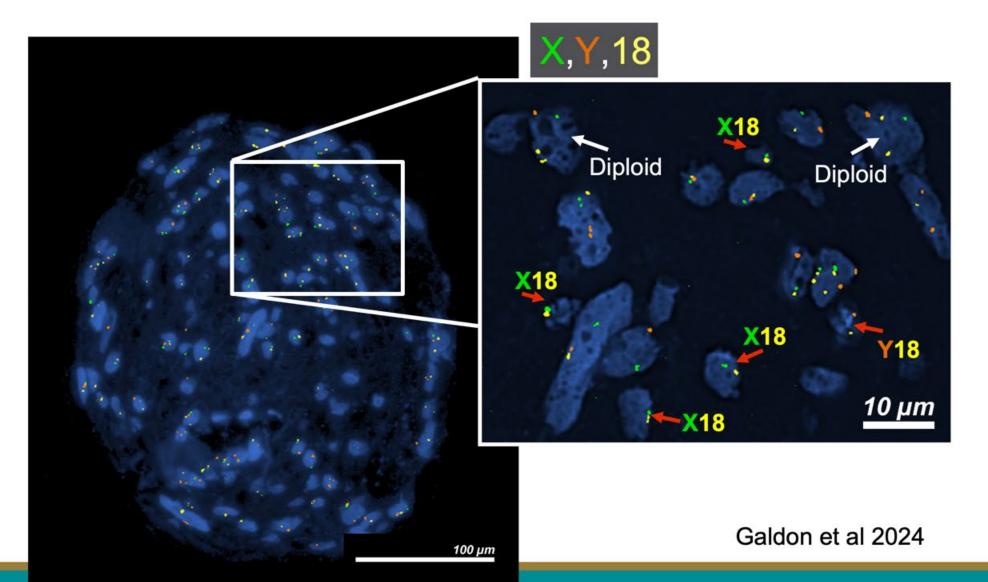




In Vitro Formed HUMAN Haploid Germ cells; DNA FISH



Human Testicular Organoid (HTO)











> Tests Biopsy Before Puberty if a clinical procedure under general anesthesia is required

Wake Forest'
School of Medicine
Institute for Regenerative Medicine

Testicular Tissue Banking
for Fertility Preservation in
Boys and Men at Risk for Infertility

> 3-Dimensional Human Testicular Organoid System (HTO) (Active Patent)

Experimental Round Spermatid Injection



Application AU2019200730A events
Priority claimed from US201161492151P
2019-02-04
Application filed by Inguran LLC
2019-02-04
Priority to AU2019200730A
2019-02-21
Publication of AU2019200730A1
2021-08-12
Application granted
2021-08-12
Publication of AU2019200730B2
Status
Active

2032-06-01

Anticipated expiration





PRS Login

ClinicalTrials.gov

Find Studies ∨ Study Basics ∨ Submit Studies ∨ Data and API ∨ Policy ∨ About ∨ My Saved Studies (0) →

Record 1 of 1 Return to Search

Home > Search Results > Study Record



The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full disclaimer for details.

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Recruiting 0

Experimental Round Spermatid Injection (ROSI) to Treat Infertile Couples (ROSI)

ClinicalTrials.gov ID NCT04298255

Sponsor 1 Wake Forest University Health Sciences

Information provided by Wake Forest University Health Sciences (Responsible Party)

Last Update Posted 1 2025-05-30





+ Expand all content

Collapse all content





Hooman Sadri, MD PhD

Cell Phone (Text Only): 336.745.7034

E-Mail: hsadri@cfi.clinic













Stanford School of Medicine ACRC

AXYS FAMILY CONFERENCE 2025

David S. Hong, M.D.

Child and Adolescent Psychiatry

Stanford University School of Medicine

Disclosures: NIH grant funding; Collaboration grant with Teleo, Inc.;

Prior Advisory Board Member to Little Otter, Inc.

Clinical Care Model

- Pediatric Endocrinology Medical Home
 - Dr. Diane Stafford Associate Chief, Division of Endocrinology and Diabetes
- Child and Adolescent Psychiatry
 - Dr. Allan Reiss Robbins Professor of Psychiatry
 - Dr. David Hong Chief, Division of Interdisciplinary Brain Sciences
 - Dr. Gisela Sandoval Child and Adolescent Psychiatrist
- Additional services:
 - Neuropsychology Dr. Tracy Jordan
 - Urology Dr. Michael Eisenberg
 - Reproductive Endocrinology
 - Pediatric Cardiology
 - Genetics Dr. Jon Bernstein







Clinical Care Initiatives

- Treatment available for all X&Y variations (e.g. 47XXY, other trisomies, Turner syndrome)
- Primarily focused on children, adolescents and young adults
 - Age range from birth-18 (but will see patients up to 25 years)
- Ongoing discussion with hospital leadership on establishing an multidisciplinary care model with experts embedded in same clinic for coordinated delivery of care



Research at Stanford in X&Y Variations

- Clinical research in Pediatric Endocrinology
 - Participation as a site in clinical trials, primarily hormone treatment studies
 - Member institution of broader proposal for RDCRN and GALAXY Registry recently submitted by Drs. Tartaglia and Davis
- Primary focus of X&Y variation research has been in the Psychiatry Department
- Within broader ACRC network, long history of translational research in neuroscience and psychiatric conditions
- Recently concluded Brain, Genes and Puberty (BGAP) Study led by Drs. Reiss and Ross
 Stanford Department of Psychiatry MEDICINE and Behavioral Sciences

Gene, Brain, and Behavior Research

The Journal of Clinical Endocrinology & Metabolism, 2024, 109, e88–e95 https://doi.org/10.1210/clinem/dgad487 Advance access publication 18 August 2023

Clinical Research Article





Executive Dysfunction in Klinefelter Syndrome: Associations With Brain Activation and Testicular Failure

Lara Judi

Judi ¹Cente Medic Alterations in Neural Activation During Facial Emotion Processing in Adolescent Male Participants With Klinefelter Syndrome

European Child & Adolescent Psychiatry (2025) 34:585–597 https://doi.org/10.1007/s00787-024-02501-y

ORIGINAL CONTRIBUTION



Associations between brain network, puberty, and behaviors in boys with Klinefelter syndrome

Rihui Li^{1,2} · Lara C. Foland-Ross · Tracy Jordan · Matthew J. Marzelli · Judith L. Ross ^{3,4} · Allan L. Reiss ^{2,5,6}

s, PhD*









Behavioral and Mental Health Data

Original Article

Cognition, Academic Achievement, Adaptive Behavior, and Quality of Life in Child and Adolescent Boys with Klinefelter Syndrome

Tracy L. Jordan, Ph Allan L. Reiss, MD*

Original Article

Social, Emotional, and Behavioral Functioning in Adolescents With Klinefelter Syndrome

Anja L. Jünger, MD*, Meagan Lasecke, MS*, Lara C. Foland-Ross, PhD*, Tracy L. Jordan, PhD*, Jamie L. Sundstrom, BS*, Vanessa Lozano Wun, MS[†], Gregory A. Witkin, PhD^{‡,§}, Chijioke Ikomi, MD^{‡,§}, Judith Ross, MD^{‡,§}, Allan L. Reiss, MD*, ¶, ¶





AXYS 2025
Family
Conference
Atlanta, Georgia

The eXtraordinarY Clinic at Emory

Sharron Close, PhD, MS, NP, FAAN, FNYAM Amy Talboy, MD, FAAP

Emory's eXtraordinarY Clinic

First & Third Fridays of the Month

All SCA variations

18-month-long waiting list for follow-ups

Priority in-schedule in case of cancellations

Clinical Focus

- Primary Developmental Evaluation
- SCA Genetic Counseling
- Key Referrals
 - Neuropsychology
 - Pediatric/Adult Endocrinology
 - Reproductive Urology and Gynecology



Emma St. Germain (above right) talks with pediatric nurse practitioner **Sharron Close** (middle) and PhD nursing student **Amy Blumling** (left).

Beyond Clinical Focus

- Emory University School of Medicine Department of Human Genetics
 - Medical Student Rotations
 - Genetic Counseling Student Rotation
- Emory University School of Nursing
 - Nurse Practitioner Student Rotations
- Southeast Regional Resource and Support Group
- Internal Emory Clinical Staff Training and Education
- Advocacy and Policy: State of Georgia

Out Their Front Door Into Ours



- Hope
- Fear
- Confusion
- Searching for Answers
- Need for
 - Acknowledgment
 - Understanding
 - Acceptance
- Need to find a Homebase

Dissemination & Awareness: Georgia Senate Visits



Leaving an Impressionand a lingering remembrance



Outside the Senate Floorwaiting to go in to be heard

Engagement and Policy Initiative: Increasing Awareness



Lt. Governor Casey Cagle, X & Y Families, Sharron Close and Senator Renee Unterman

May is X & Y Chromosome Awareness Month!





Governor Nathan Deal with Patients and Families along with our Emory Team

