

Where Ethics, Compliance, Diversity & Rural Health Research Intersect!

Health Care Compliance Association ~ Research Compliance Conference
Phoenix, AZ, June, 2023

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Objectives

1. Describe the current landscape of rural health research and identify key stakeholders
2. Understand where rural health research intersects with human subjects protections (IRB review), compliance, diversity, and ethical principles
3. Identify actionable steps for sites, sponsors, and other key stakeholders for engaging and supporting rural sites

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Speakers



- Kylie Sands, MBA, CCRP
- Clinical Research Operations Manager
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Kylie Sands has approximately 12 years of experience in healthcare. She began working in ophthalmology as a technician and then a surgical coordinator, surgical assistant and laser technician. She then began her career in Clinical Research in retina in Washington DC and has worked at the St. Lawrence Health Clinical and Rural Health Research Department since 2017.

Kylie obtained a Bachelor of Science from State University of New York at Potsdam and a Master of Business Association from Northcentral University with a specialization in Healthcare Administration. She also received a certificate in Data Analytics from General Assembly and is a Lean Six Sigma Greenbelt. She is a Certified Clinical Research Professional through the Society of Clinical Research Associates (SOCRA) and is the NY Chapter co-chair for the SOCRA organization.

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Speakers



Wendy Portier, MSN, RN, CHC, CHRC, CPC
Consultant
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Wendy Portier has over 25 years of experience in health and managed care including: Health Care Compliance, Research Compliance, Consulting, Clinical Research, Critical Care Nursing, Quality, Utilization Management, Case Management and Disease Management. Having worked on the provider, researcher, payer and sponsor sides, Wendy has a unique perspective and extensive knowledge regarding clinical research compliance. Her specific research compliance experience includes: implementing process improvements, building/re-designing Clinical Trials Offices, leading government inspections & responses, auditing, monitoring, implementing compliance programs and improving the research billing revenue cycle – from coverage analysis & budgets, authorizations, charge/claims review to denials & appeals management.

Wendy obtained a Bachelor of Science in Nursing from Nicholls State University and a Master of Science in Nursing in Clinical Research Management from Duke University. She also completed a Health Care Corporate Compliance - Post Graduate Certificate Program at George Washington University in Washington, DC and holds several health care related certifications. Wendy has lectured locally, nationally and internationally on various topics related to clinical research, health care auditing and health care compliance.

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Acknowledgements

- Carly Lovelett, MBA, CCRP, CRCP
 - Senior Director of Regional Operations
 - Headlands Research
- Jessica Rowe, MA, MS, CCRP
 - Associate Director, Yale Center for Clinical Investigation,
 - Human Research Protection Program, Research, Compliance, and Quality
 - Yale University

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Rural America

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Rural America

“ ‘Rural America’ is a deceptively simple term for a remarkably diverse collection of places. It includes nearly 72 percent of the land area of the United States and 46 million people. Farms, ranches, grain elevators and ethanol plants reflect the enduring importance of agriculture.”



Image source: Another Step Towards Closing the Digital Divide in Rural America | NCTA — The Internet & Television Association
Where is 'rural America' and what does it look like? (thecoalition.com)

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Rural America Defined

Rural = Counties outside of metro or micro areas

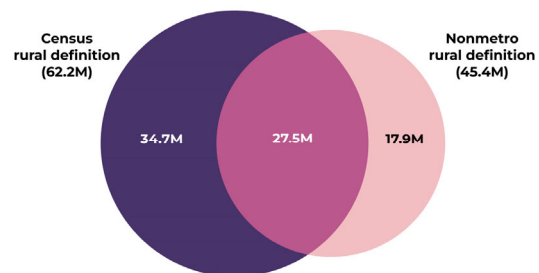
- Metro area = 50,000 or more people
- Micro area = 10,000-49,999 people
- *Health Resources and Services Administration (HRSA)/Office of Management and Budget (OMB)*

Rural = any area that is not urban

- Urbanized Area (UAs) = 50,000 or more people
- Urban Clusters (UCs) = 2,500-49,999 people
- *United States Census Bureau*

Each rural definition counts people and places differently

Census rural and nonmetro population overlap



Source: ACS 2019 5-year estimates. Census rural definition estimates are derived from 2010 census block definitions and population estimates. Nonmetro rural definition estimates are calculated using 2019 Core-based Statistical Area (CBSA) classifications.

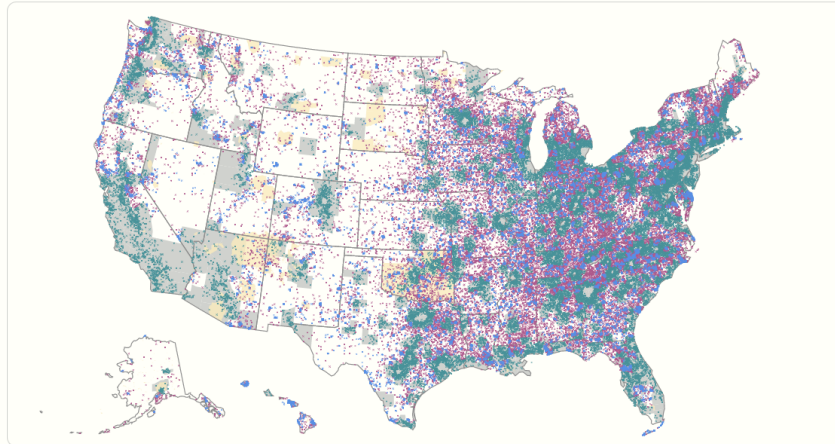
CENTER ON RURAL INNOVATION

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The populations counted as rural under both definitions are concentrated in the eastern half of the U.S.

One dot equals 1,000 people

Metro fringe Open lands Small towns Metro counties Native lands



Source: ACS 2019 5-year estimates. Density estimates are derived from 2010 census block definitions and population estimates. Metro/nonmetro estimates are calculated using 2019 Core-based Statistical Area (CBSA) classifications. Native lands are 2019 American Indian Area Geographies published by the U.S. Census Bureau.

CENTER ON RURAL INNOVATION

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Rural America: Characteristics

Sparsely populated

Low housing density

Far from urban centers

Pre-tax income is approximately \$50k compared to \$72K in urban households

High population of retirees

[Rural America Statistics: Rural vs Urban Definition and More – MODERN COUNTRY LIVING](#)
The United States Census Bureau - What is Rural America? 2017. Accessed March 23, 2022.
<https://www.census.gov/library/stories/2017/08/rural-america.html>
[Where is 'rural America,' and what does it look like? \(theconversation.com\)](#)

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Rural America Has An Older, Sicker and Poorer Population

OLDER The median age of adults living in rural areas is greater than those living in urban areas.

Area	Median Age
RURAL	51 years
URBAN	45 years

18.4% of rural Americans are age 65+ versus **14.5%** of urban Americans.

SICKER: Rural areas have higher rates of several health risk factors and conditions.

Risk Factor	RURAL	URBAN
OBESITY	33.5%	28.0%
DIABETES	12.6%	9.9%
SMOKING	28.5%	25.1%

POORER: Nationally, rural households had lower median household income.

Area	Median Household Income
RURAL	\$49.9K
URBAN	\$66.1K

Below the Line
14.7% of the rural population is below the poverty line, compared to **11.3%** of the urban population.

Who lives in rural America?

- Sixty-million people in the U.S. or 1 in 5 Americans
 - 19% of America's population
 - 20% of population 65 and older
- *"If you've seen one rural community, you've seen one rural community."*

NIHCM Share

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Racial & Ethnic Diversity in Rural US Grows by Nearly 20%

FIGURE 1. NONMETROPOLITAN POPULATION BY RACE AND HISPANIC ORIGIN, 2020

Race/Ethnicity	Percentage
White	~65%
Hispanic	~15%
Black	~10%
Native/Other Race	~5%
Asian	~2%
Multiracial	~2%

Rural White population declined in the last decade while non-White population increased.

There was a substantial increase in the share of the rural population that is Hispanic, Black, Indigenous, or some other race.

Note: Hispanic category includes Hispanics of any race. All other categories include only non-Hispanics.
 Source: U.S. Census 2020.

Johnson, K. & Lichter, D., Growing Racial Diversity in Rural America: Results from the 2020 Census, University of New Hampshire, May <https://carsey.unh.edu/publication/growing-racial-diversity-in-rural-america> 25, 2022

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Rural Health

Disparities

- Often characterized by indicators such as:
 - High incidence of disease or disability
 - Increased mortality rate
 - Lower life expectancies
 - Higher rate of pain and suffering

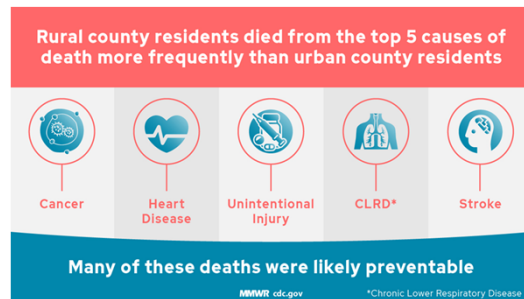
Life Expectancy at Birth in the U.S., 2010-2014

County Urbanization	Total Population	Males	Females
Rural Nonmetro	77.0	74.5	79.7
Urban Nonmetro	77.2	74.8	79.7
Small Metro	78.3	75.9	80.8
Medium Metro	78.9	76.5	81.3
Large Metro	80.0	77.6	82.4

Source: Singh, G.K., Daus, G.P., Allender, M., et al. 2017. *Social Determinants of Health in the United States: Addressing Major Health Inequality. Trends for the Nation, 1935-2016.* International Journal of Maternal and Child Health (IJMCH) and AIDS, 6(2), 139-164.

Higher rates

- Compared to urban residents, people living in rural areas are more likely to die from heart disease, cancer, unintentional injury, chronic lower respiratory disease, and stroke.

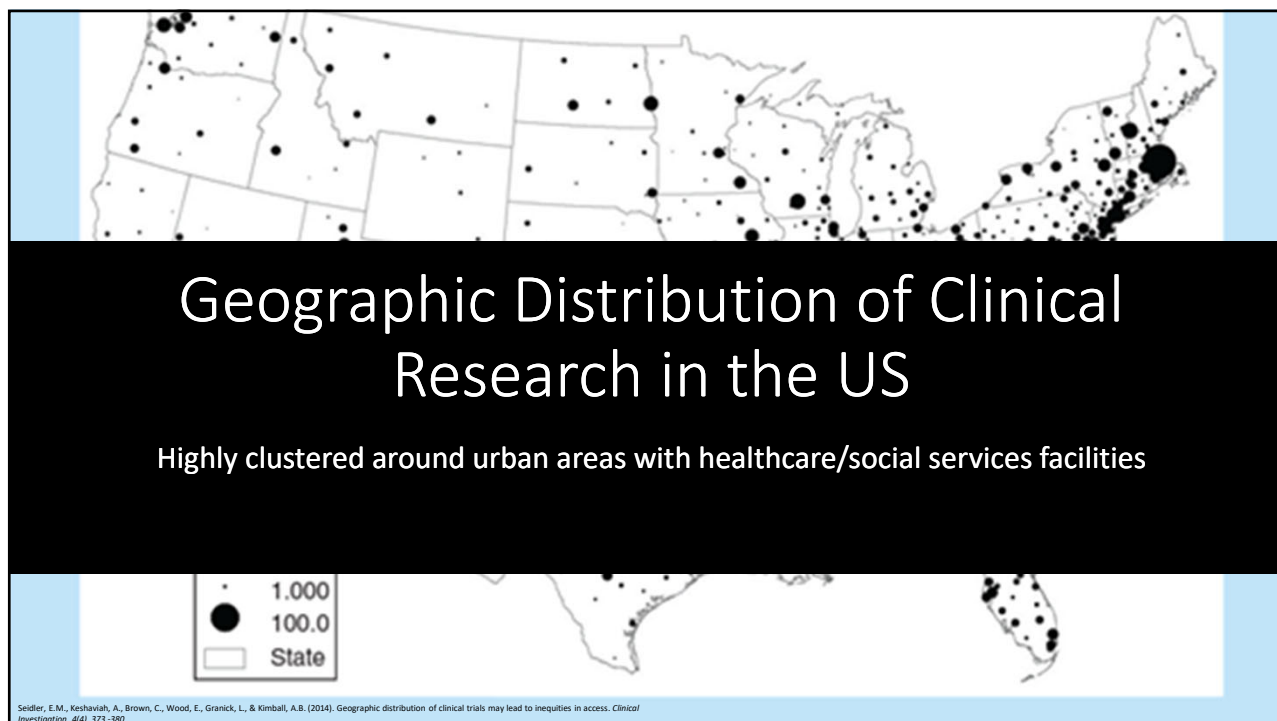


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Health Disparities Risk Factors

- Lower socioeconomic status
- Limited access to medical services (including specialists and tertiary care)
- Geographic isolation
- Unreliable transportation
- Limited access to childcare
- Higher rates of risky health behaviors
- Higher rates of uninsured population
- Low health literacy
- Financial challenges

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Food & Drug Administration

Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability

Draft Guidance for Industry
APRIL 2022

The purpose of this guidance:

- To provide recommendations to sponsors developing medical products on the approach for developing a
- Race and Ethnicity Diversity Plan (referred to as the “Plan”)
- To enroll adequate numbers of participants in clinical trials from
- Underrepresented **racial and ethnic populations** in the United States.

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Ethical Obligation

Justice: equal distribution of benefits and burdens

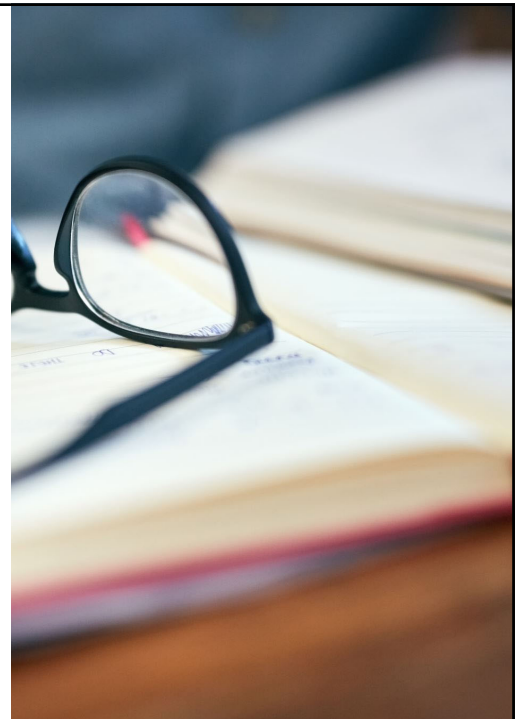
“moral requirements that there be fair procedures and outcomes in the selection of research subjects” –Belmont Report



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Clinical Research Key Stakeholders

- Institutional Review Boards (IRBs) / Ethics Committees
- Sponsors (Drug & Device Companies)
 - Protocol Writers
- Contract Research Organizations (CROs)
- Clinical Teams / Sites
 - Investigators / Clinical Research Coordinators
- Subjects / Study Participants
- Regulatory Authorities
- Others



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Diversity, Equity & Inclusion



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Diversity in Clinical Research

- “People may experience the same disease differently. It’s essential that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities benefit from scientific advances.” - [National Institute on Minority Health and Health Disparities](#)
- Diverse representation is necessary to identify effective treatments for all individuals.



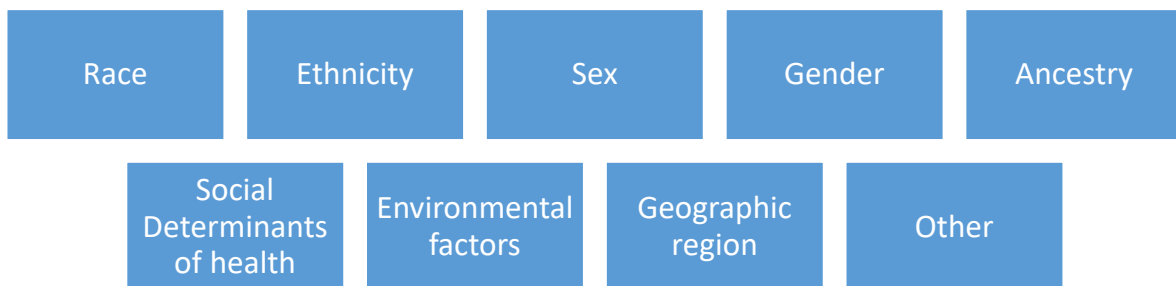
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Diversity in Clinical Research

- Ensure that all potential participants have equal opportunity to benefit from treatments under investigation
- Ensure the most accurate representation of the population as possible
- Improve patient care and safety
- Increase our understanding of diseases and how they impact different groups of people
- Identify potential side effects for different groups of people

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What is Diversity?



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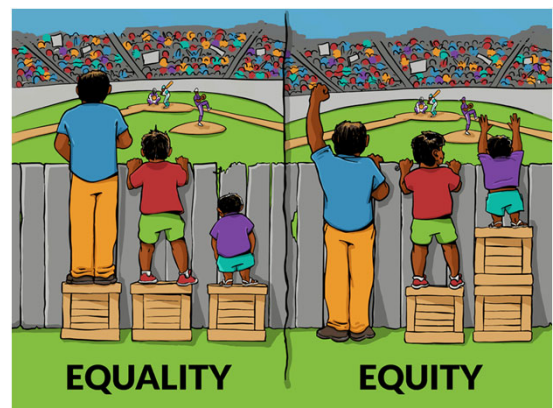
Social Determinants of Health

- Economic Stability
- Education
- Unemployment/Job Insecurity
- Food insecurity
- Health care access and quality
- Housing Insecurity
- Social inclusion and non-discrimination

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Equity

Fair treatment for all people, so that the norms, and practices in place ensure identity is not predictive of opportunities. Equity differs from equality in a subtle but important way. While equality assumes that all people should be treated the same, equity takes into consideration a person's unique circumstances, adjusting treatment accordingly so that the end result is equal.



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Equity

- “There’s a real difference between equal and equitable. Suppose we said, ‘All interns are created equal. We pay them nothing.’ The people who can afford an entire summer without getting paid are likely already coming from a position of privilege.”- Bill Schaninger, McKinsey & Company
- When taking into account barriers such as ability to travel, finances, etc. It’s important to meet patients where they are rather than forcing them to travel to be able to participate in trials.

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Inclusion

- It's essential that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities can benefit from scientific advances.
- People experience the same disease differently. It’s important to have different representation in a trial to gain insight to the disease process and potential treatment interactions

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Inclusion

- People from Racial and Ethnic Minority Groups
- Sexual and Gender Minority Populations
- Socioeconomic Status
- Ageism

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Special considerations for HSP

- Decreased health literacy
- Under insured or un-insured
- Economically disadvantaged/poverty
- Limited internet/cellular access
- Little to no public transportation options

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My Why

St. Lawrence County, New York



- Waterfall image: <https://www.visitstlc.com/waterfalls-guide/>
- Potsdam, NY Image: <https://www.travellens.co/best-things-to-do-in-st-lawrence-county-ny/>

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St. Lawrence Health

- Located in rural St. Lawrence County, NY
- Comprised of 3 hospitals and outpatient clinics
- Closest tertiary medical center: >2.5 hours
- Total inpatient capacity: 144 beds
- Research department founded in 2015



Image from: <https://www.whsv.com>

Health Indicator	St. Lawrence County	New York State Average
Primary Care Physicians	1,860:1	1,180:1
Mental Health Provides	460:1	310:1
Preventable Hospital Stays	4,327	3,717
Adult Smoking	21%	13%
Poor or Fair Health	19%	16%
Poor Mental Health Days (per 30 days)	5.1	3.9
Adult Obesity	35%	27%
Access to exercise opportunities	42%	88%

Data from: [St. Lawrence County, New York | County Health Rankings & Roadmaps](#)

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Snapshot of St. Lawrence County

	St. Lawrence County		
Size	2,680 Square miles (largest county in the state, larger than Delaware)		
Population of St. Lawrence County	108,051		
Population/sq. mile-SLC (Avg)	40.5	Population/sq. mile in urbanized areas (Avg)	2,534.4
Race			
White	93.6		
Black	2.6		
Indian/Native	1.1		
Asian	1.1		
Hispanic	2.4		

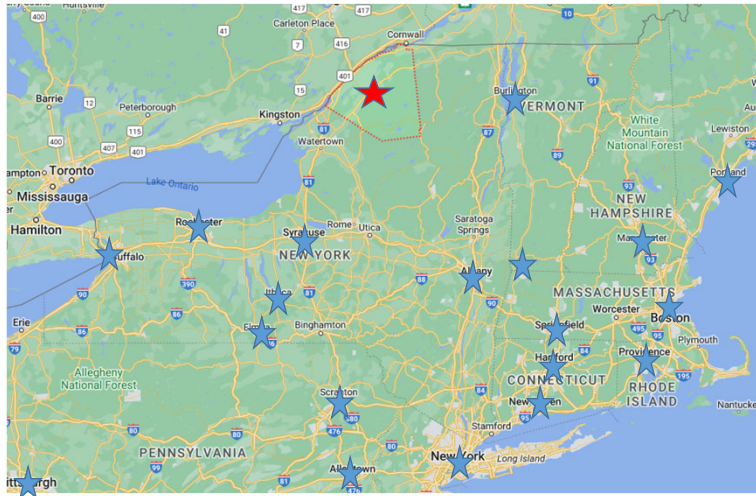
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Snapshot of St. Lawrence County

	St. Lawrence County	National Average
Percent with High school or higher education	88.6%	89.4%
Percent with Bachelor's degree or higher	23.6%	35%
Median household income	\$54,351	\$69,717
Percentage of uninsured adults	5.5%	8.6%
Percentage of adults insured on Medicaid	10.3%	9.3%
Percentage of children in poverty	26.6%	16.9%
Total Percentage in poverty	18.9% (second worst in the state)	12.8%

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SLH Clinical and Rural Health Research provides a bridge for those who cannot travel out of SLC.

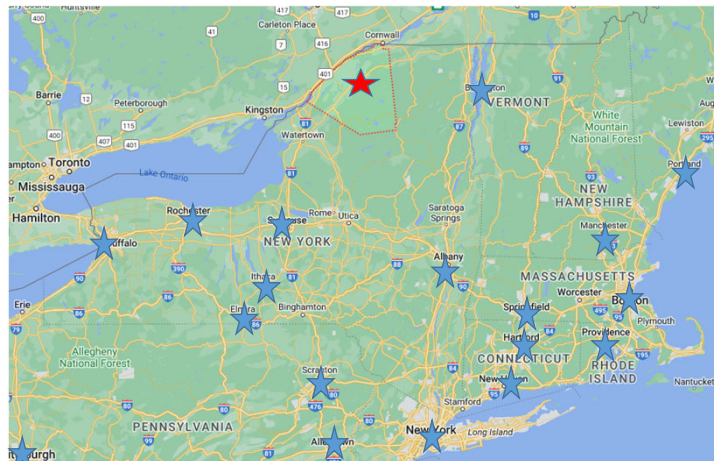


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SLH Clinical and Rural Health Research provides a bridge for those who cannot travel out of SLC.

- **Travel time to other clinical trials regions/sites often exceeds 3 hours**
- **Can be up to 6+ hours should you need to get to NYC or Boston.**



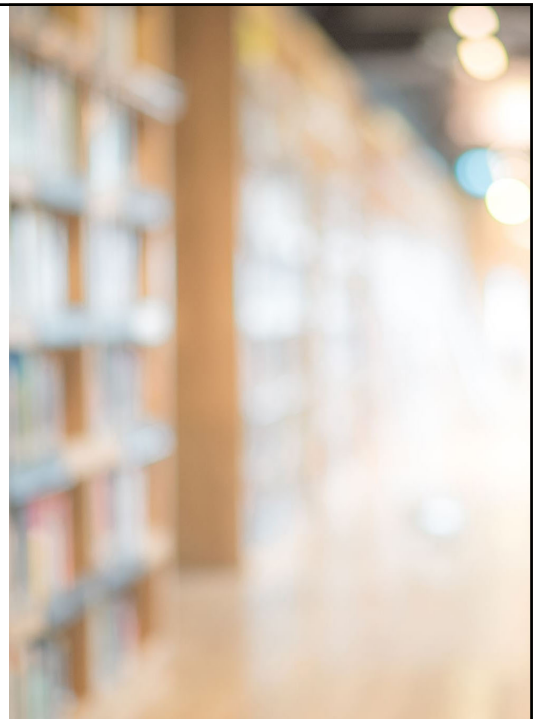
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Challenges, Risks & Action Steps

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Challenges to Conducting Research in Rural America

- Sponsor:
 - Distance to site
 - Limited transportation options
 - Lack of established reputation
- Organizational:
 - Lack of understanding / expertise
 - Conflicting priorities
 - Missing structure/incentives/time for clinics and providers
 - General lack of resources: time, personnel, experience, equipment, space, pharmacy availability, software, etc.
- Patient:
 - Access to transportation
 - Access to childcare
 - Time to devote to travel and long research visits
 - Awareness/understanding of research and available trials
 - Distrust in healthcare/research



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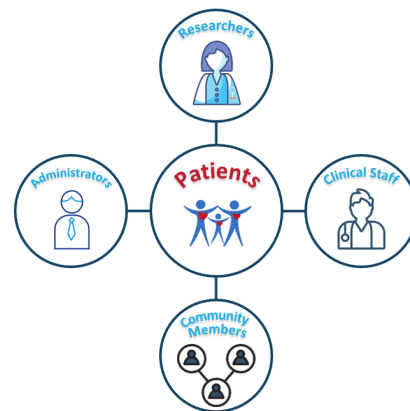
Risks to Conducting Research in Rural America

- Research Billing
- Human Subject Protection / Institutional Review Board (IRB)
 - Internal versus Central
- Health Information Portability & Accountability Act (HIPAA)
 - Research & HIPAA Privacy compliance requirements
 - Authorization / Waiver of Authorization / Partial Waiver determinations
- Food & Drug Administration compliance requirements
- Conflict of Interest / Research Misconduct
- Liability
- More...

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Solutions & Lessons Learned

- Invest in workforce and continuing education
- Implement policies, procedures, tools & templates
- Embrace Technology
- Track Key Performance Indicators (KPI)
- Educate organizational leaders; inform on benefits of research
- Celebrate & Communicate Successes
- Engage the community
 - Provide educational opportunities
 - Be flexible with scheduling when possible
 - Negotiate budgets with patients in mind
- Highlight rurality as diversity
- Network with Sponsors, CROs, sites
- Seek out experts / help
 - Universities
 - Consultants



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Action Steps for Sites, Sponsors & Other Key Stakeholders for Engaging & Supporting Rural Sites



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Sites: Workforce Development

- Develop workforce pipeline
- Offer free / low-cost training – operational and compliance
 - University resources
 - IRB resources
 - Dangerous Goods Training – Mayo
- Create formal onboarding plans
- Seek mentors at experienced sites, Universities, IRBs



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Onboarding Plan

NAME:				
Job Title:	Instructions			
Badge #/Employee#:				
Start date:	Some of the tasks in this column can be designated	Remove or update items in BLUE, as applicable		
Direct Report NAME:	Insert Actual Name/Title for each line item		Person who completes the task	
Task	Assigned To Name/Job Title	Date Completed	Initials	Comments / Additional Instructions / Notes

Pre-Start | General - ALL STAFF | NEW | Research Nurse | Study Coordinator | Research Assistant | Regulatory Coordinator | Contract Analyst | **Finance Analyst**


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Sponsors, IRBs & Other Experienced Sites

- Offer clinical research and compliance training programs
- Mentor new sites / staff
- Give constructive feedback
- Share documents, tools, templates, etc.



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Sites: Leverage remote options with sponsors

- Become early adopters of technology
 - eRegulatory
 - eSource
 - Remote temperature loggers
- Electronic Medical Records remote access

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Sites: Informational documents for visits

- Create an informational one-pager for sponsors
 - Include information regarding site capabilities
 - Emergency services
 - Temperature monitoring
 - Drug storage/laboratory capabilities
- Create a virtual site tour to take advantage of remote visits for Site Selection and/or Site Initiation
 - Include Pictures of drug storage/temperature monitors (including expiration dates)
 - Facilities, etc.



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Sites: Make travel as easy as possible for Sponsors

- We created a “travel info for monitors” document outlining the closest airports, their distance, and pros/cons to each (rental car counter, tiny 6 seater airplanes, must have rental car delivered to airport, etc.)
- We also include hotels and restaurants for their information

ST LAWRENCE HEALTH
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Air Travel and Rental Car information

Airport Name	Distance from Site	Rental Cars	Other Information
Syracuse Hancock International Airport (SYR)	138 miles (2.5 hrs)	Onsite rental counters	<ul style="list-style-type: none"> • Most recommended • Many direct flight options
Ottawa International Airport (YOW)	80.7 miles (1 hr 45 min)	Onsite rental counters	<ul style="list-style-type: none"> • Large international airport with direct flight options • Will cross into the US via customs, need passport but typically very quick and easy
Caldwellsburg International Airport (CDS)	30.2 miles (1 hr)	Hertz Rental 1-800-654-3131 www.hertz.com	<ul style="list-style-type: none"> • Direct flights to Philadelphia, PA daily • Need to arrange rental prior to travel so it can be delivered to airport for you
Watertown International Airport (ART)	77.4 miles (1 hr 30 min)	<ul style="list-style-type: none"> • Enterprise Car Rental 18943 US Route 11 Watertown, NY 13601 315-782-0100 • Hertz Car Rental 17940 US Route 11 Watertown, NY 13601 315-782-2635\ • Rent-A-Wreck 800-464-8412 	<ul style="list-style-type: none"> • Direct flights to Philadelphia twice daily • Small airport • Need to arrange rental prior to travel so it can be delivered to airport for you
Massena International Airport (MSS)	20.7 miles (30 min)	<ul style="list-style-type: none"> • https://www.mahoney@domall.com/rental-car-service • Enterprise Rent-A-Car 6805 New York 56, Potsdam, NY 13676 (315) 265-0700 www.enterprise.com • Countrywide Rent-A-Car 7513 US Highway 11, 	<ul style="list-style-type: none"> • Three direct flights daily to Boston • Very small airplanes, 6 seats • Often experiences delays or cancellations due to weather • Need to arrange rental prior to travel so it can be

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Sites: Build your reputation

- Keep communication open and respond to emails
- Quick turn around for regulatory documents/contracts/budgets
- Quality Data entry, query resolution
- **Ultimately** do your best to be a consistent and pleasant site to interact with, keeps sponsors returning
- “You are my most difficult site to get to, but my favorite to come visit”



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Summary

- Representation matters!
 - Clinical research participants
 - IRBs, Committees, etc.
- Everyone has a role!
 - Compliance
 - Executives
 - Operations
 - IRBs
 - Sponsors/CROs
 - Large/Academic Sites
 - Individuals
- The future is bright for rural sites and patients:
 - Decentralized clinical trials
 - Remote monitoring
 - Telehealth
 - Real world evidence



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