



May 29, 2013

NHGRI Genomic Medicine V

**Building a personalized genomic
medicine program in a community health
system:
*Opportunities and Challenges
at Mission Health***

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Who is Mission Health?

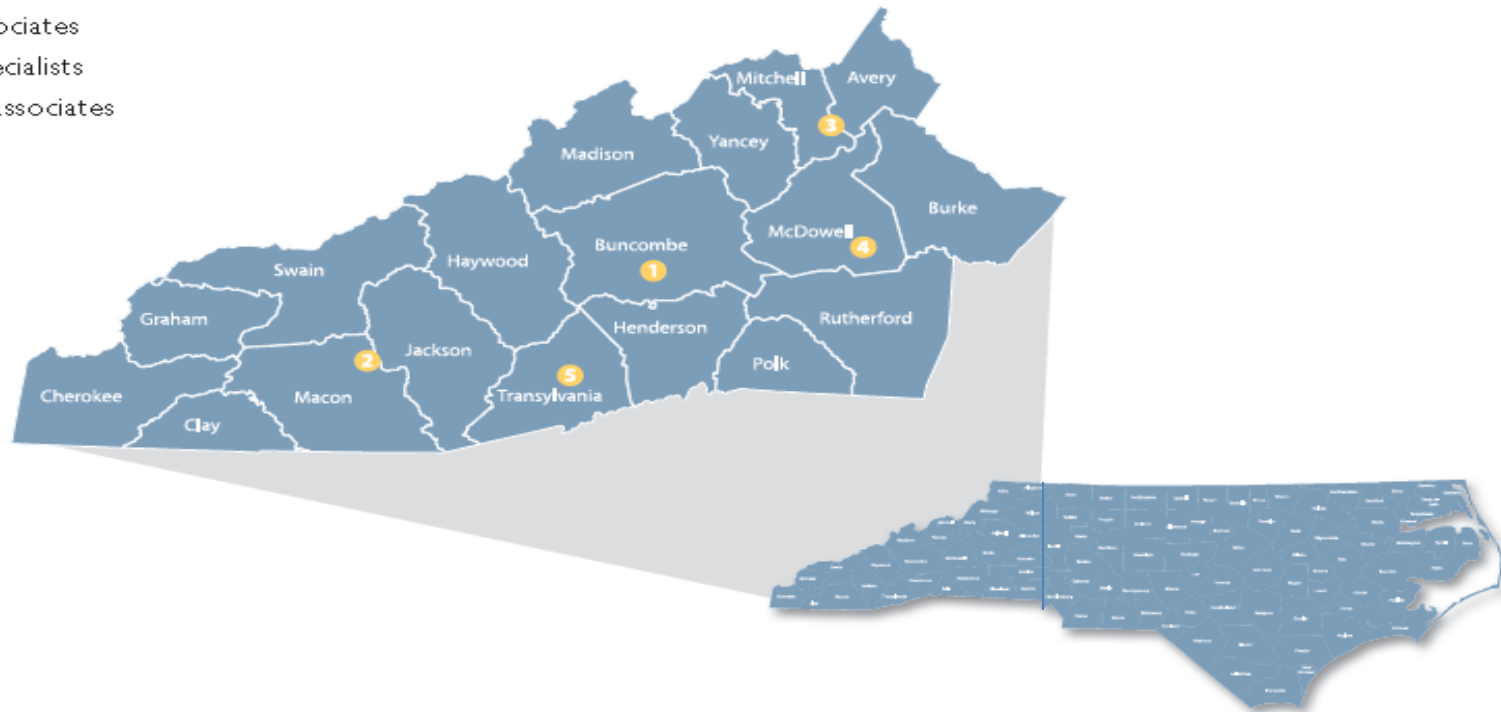
Non-profit rural health care system, WNC



The Mission Health Footprint

- 19 counties in Western North Carolina -

- 1 Asheville Surgery Center
Cancer Care of Western North Carolina
Carolina Spine and Neurosurgery Center
Fullerton Genetics Center
Hope Women's Cancer Centers
Mission Hospital
Mission Children's Hospital
Mission Medical Associates
Regional Surgical Specialists
Victoria Urological Associates
- 2 Angel Medical Center
- 3 Blue Ridge Regional Hospital
- 4 McDowell Hospital
- 5 Transylvania Regional Hospital



Mission Health System

Mission Hospital

- Flagship, tertiary care regional referral center
- 750 bed hospital

Six smaller hospitals

- Throughout mountains
- 300 beds

Patient demographic

- Largely underserved
- Mostly caucasian
- Stable population
- 75% Medicare/Medicaid

Highly rated quality care:

- Truven/Thomson Reuters: Top 15 health care system
- Mission Hospital
 - Truven:Top 100 hospitals
 - 95th percentile value based purchasing
 - NC: busiest surgical hospital
 - High ratings in cardiology, orthopedics, pediatrics
- Transylvania Hospital
 - Top 100 Critical Care Access

Personalized Genomic Medicine at Mission

Current vision:

- Infrastructure for genomic medicine
 - Education: HCP, pts
 - Integration: pharmacy, genetics, pathology services
 - HIT/EMR/CDS
- Pharmacogenomic testing (DGI)
 - Germline/Somatic

Future potential:

- Integrated holistic approach
 - Omic medicine
 - Genetics of common disease
 - Pyscho-social, cultural, economic
 - Wellness, access, coordination and accountability of care

Senior Leadership support:

- **Ronald A. Paulus, MD, MBA**
President and CEO of Mission Health
- **Jill Hoggard Green, PhD, RN**
President, Mission Hospital
- **Dale Fell, MD**
Senior Vice President and System CMO
- **Kathy Guyette, RN, MSN, CNE-BC**
Senior Vice President, Patient Care Services
- **William Maples, MD**
Senior Vice President and Chief Quality Officer
- **Sulaiman H. Sulaiman**
Senior Vice President and Chief Information Officer

Why should Mission develop a Personalized Genomic Medicine Program?

- It's the right thing to do for our patients and community
 - Mission's patient-centered-care philosophy
- Prepares hospitals, clinicians, and patients in WNC for era of genomic medicine
 - Provides cutting edge quality care for every patient, locally
- Builds on existing expertise in molecular genetics
 - Mission Fullerton Genetics Center

Mission Fullerton Genetics Center

Critical regional resource

- Expert team of clinicians and laboratory staff address spectrum of diseases
 - Developmental disorders, autism, metabolic conditions, high risk pregnancy, adult onset disorders, inherited cancer...
 - Telemedicine

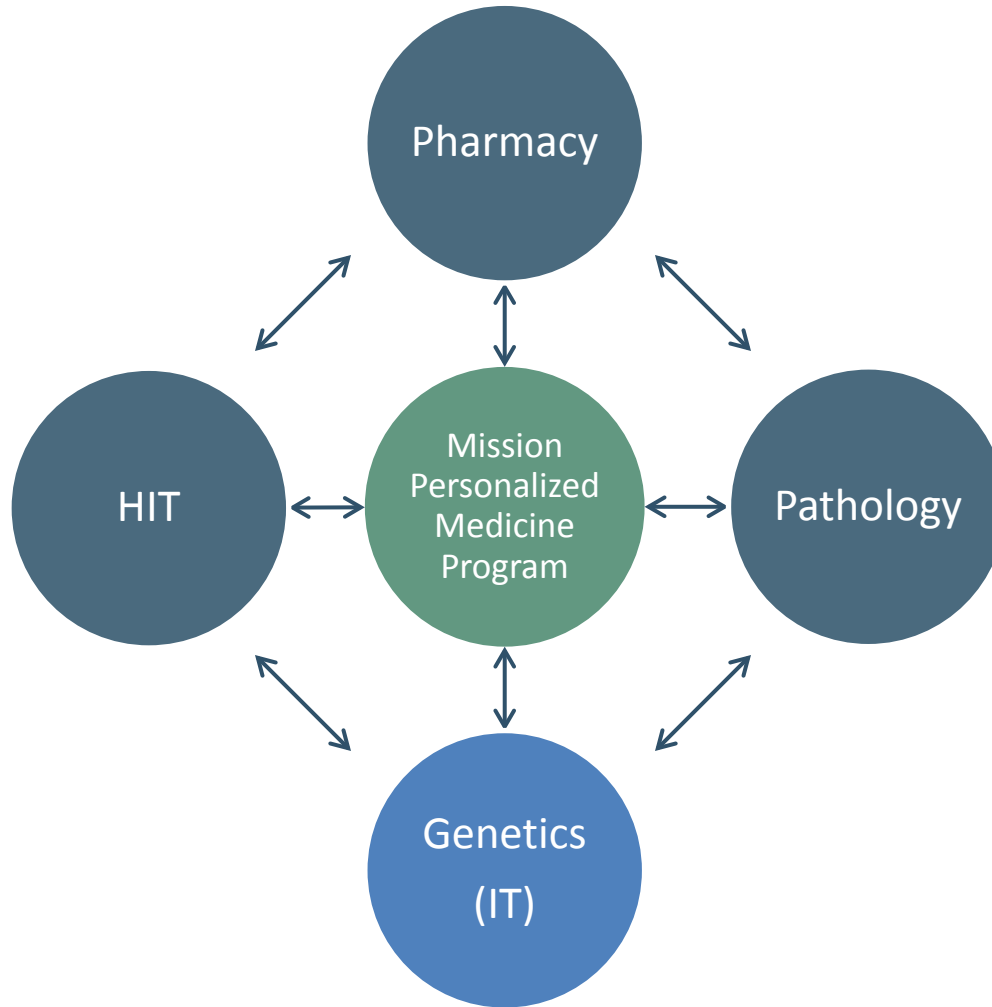
Expert genetics laboratory

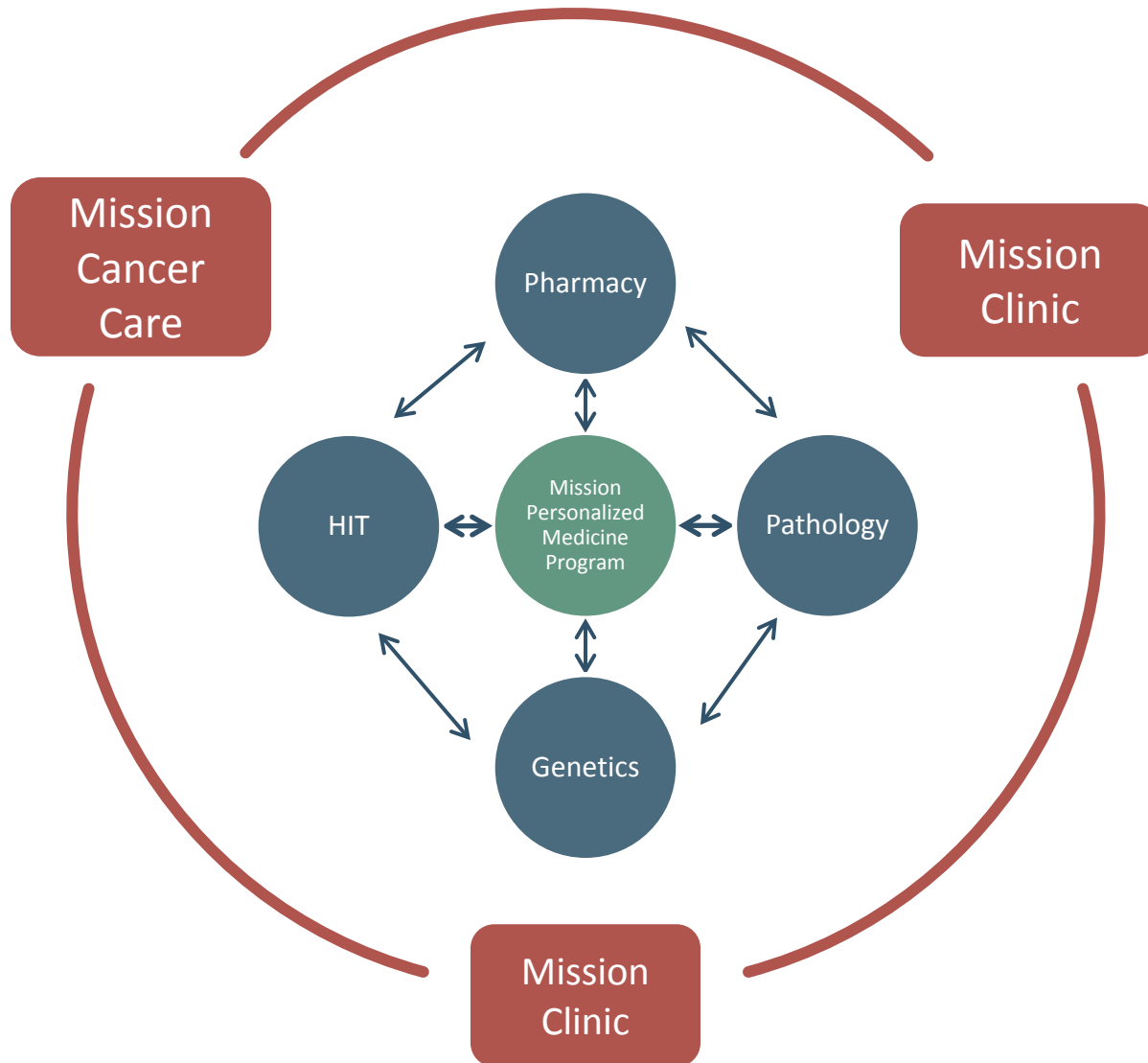
- Serving WNC, US, internat'l
- Molecular and genetic testing/technology
 - Methylation specific PCR
 - Targeted DNA genotyping
 - High density cytoscan arrays
 - Triplet repeat amplification
 - Sanger sequencing
 - NGS Illumina MiSeq
- Team approach for interpretation, diagnosis, treatment

*Team: Lab Directors: J Tarleton, H Kearney, J Kearney

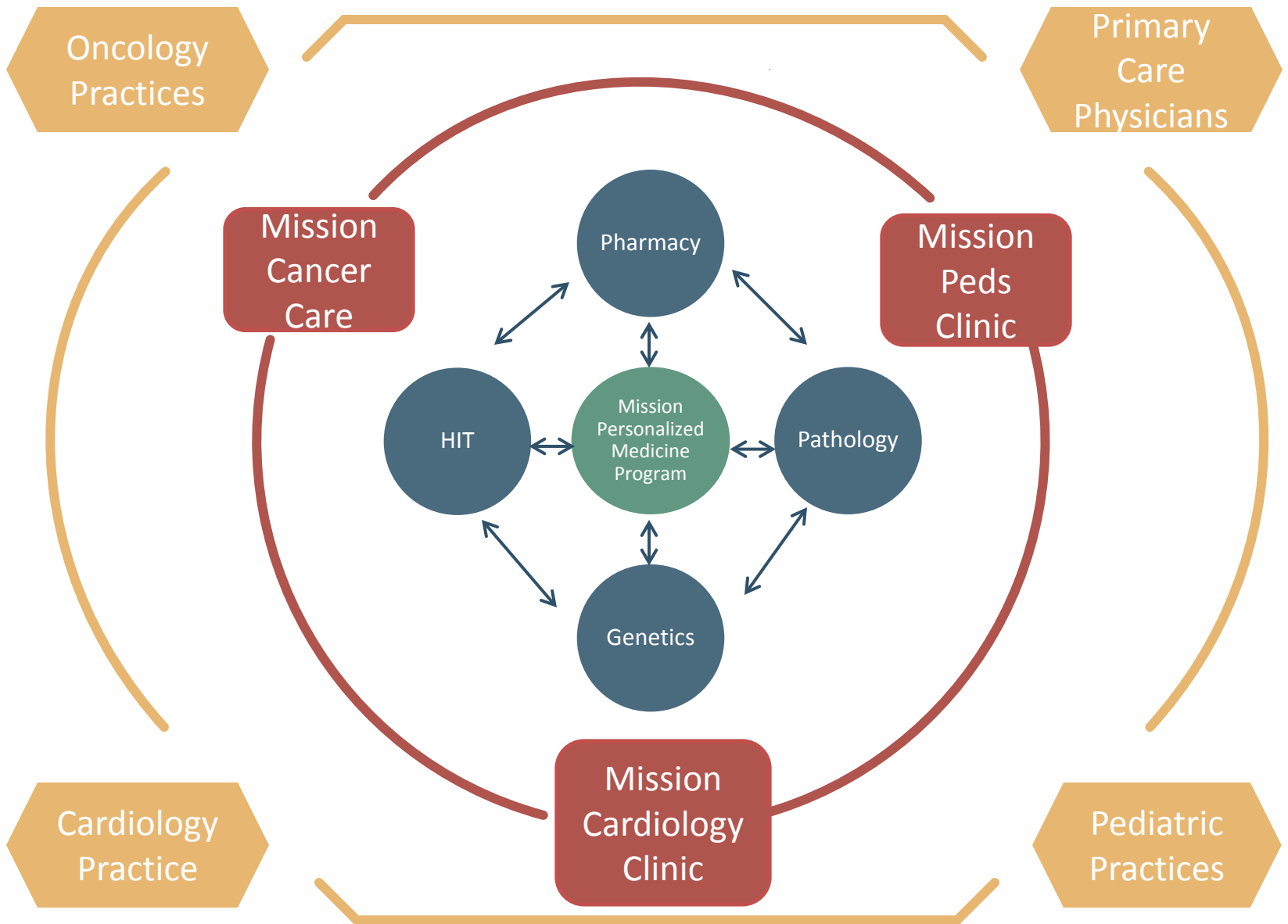
Clinical: Bill Allen, Ellen Boyd, 5 genetic counselors, social worker

-Strong infrastructure-





Challenges/Opportunities of a non-academic health system



Challenges/Opportunities of a non-academic health system

Developing the appropriate, integrated infrastructure to support the program

- **Awareness, education, communication, dissemination, ELSI**
 - For the health care provider, staff
 - For the patient, family, public, policy makers
- **Laboratory testing, interpretation, application**
- **EMR integration of genomic results and CDS tools**
 - Cerner system, inpatient vs outpatient
- **Archiving/monitoring non-reported results**
- **CMS reimbursement**
- **Cost-benefit, economic return on investment analysis**
- **Impact, evaluation, outcome measures**

Building a Genomics Medicine Program at Mission

- **Phase I: Assessment**
- **Phase II: Planning***
- **Phase III: Implementation**
- **Phase IV: Evaluation**
- **Phase V: Expansion/CQI/Evaluation**

Building a Personalized Genomic Medicine Program at Mission Health

- **Phase I: Assessment (internal and external)**
 - Evaluation of buy-in, infrastructure, feasibility
 - HCP familiarity, interest, knowledge
 - Resources and capacity
 - HIT, EMR, IT, Pharmacy, Pathology, Genetics
 - Environmental assessment:
 - Data collection: inpatient at Mission Hospital
 - Regional health conditions

Overall: considerable support, buy-in, infrastructure, patient need; proposed demonstration projects

Proposal for pilot quality improvement initiatives

1. Mission Hospital Pharmacy (in-patient)

- PGx testing for drugs w FDA black box warning (especially HLA markers)
- Across service lines and practices: education, interpretation, application, EMR, HIT
- Testing using outside lab, then bring most in-house
- Pre-emptive vs POC?

Proposed Pilot QI Projects

2. Cardiology (stent patients: 1200/yr)

- Pre-op/pre-emptive testing CYP2C19 for clopidogrel
- Mission Asheville Cardiology practice serves region
- Data related to complications, readmissions, ED visits due to cardiac events
- Single test vs panel? Reimbursement rate?
- Impact: adoption, practice pattern changes, reducing cardiac events, risk avoidance, reducing cost of care

Proposal for pilot QI initiatives (cont)

3. Mission Cancer Care: (3,000 cancer patients)

- New Cancer Center (2012)
- Affiliated with University of North Carolina Lineberger Comprehensive Cancer Center
- Best practices for tumor marker testing
- Streamline process for tumor marker testing
- Integrated lab report from multiple labs/tests

Phase II: PLANNING

Phase IIA: Planning, Implementation, Evaluation of pilot QI projects

- Prioritization (cardiology?)
- Timeline: 1-3 years
- Budgets, Proforma

Phase IIB: Overall planning for genomic medicine program (short and long term)

- Strategic plans
- Business plans

Challenges in Implementation*

Where does Mission stand?

Got it covered(?)

- Institution acceptance
- (Clinician acceptance)
- (Clinician understanding)
- Access to expertise and testing (GM)
- Genomic applications
- FU of genotyped patients
- Outreach to at-risk family
- Consent
- Access to controls
- Biobanking

Challenging/Need help

- Conflicting benefit/value
- EMR integration/CDS
- Understanding by patient, family, public
- Reimbursement estimates
- ROI
 - Cost benefit analysis? **
 - Cost minimization analysis? **

*Manolio T, et al, GIM, 2013

**Veenstra, D L, Genomics and Personalized Medicine, 2nd ed. 2013

Practical Challenges:

- Vetting gene-drug interactions:
 - *CPIC, CRVR, Mission Expert Advisory Council*
- Process for archiving data, monitoring actionability:
 - *Evaluation of current/new commercial programs*
- Strategy for pre-emptive testing:
 - *How pre-emptive? High risk models vs all-comers*
- Testing in-house vs outside labs:
 - *Quality, individualized care, time/cost effectiveness*
- Timing/transition of genotyping to sequencing
 - *Implications for clinical, HIT integration, ELSI*
- Models/metrics for economic analysis, impact
 - *Outcome data to be collected, compared for impact*

It takes a village, with partners!

- Lesson learned, common threads, unique issues
- Strategy for expansion, sustainability and growth
- Pathways and systems vs distinct diseases, treatments
- Rapid learning systems
 - Learning from daily clinical experience
 - Integrating knowledge bases from all sources



MISSION HEALTH AIM:

*“Getting each patient to their desired outcome,
Without harm, without waste,
And with an exceptional experience.”*

Thank You!

Questions and Comments?

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Mission Fullerton Genetics Center