

A Collaborative Research Partnership Between the Salt River Pima-Maricopa Indian Community and the Translational Genomics Research Institute

- SRPMIC was committed to finding solutions that would impact the prevalence of diabetes and resulting complications from the disease.
- Partnered with Tgen
- SRPMIC developed a way to express sovereignty over research through the contract and research code, which are model template documents.
- SRPMIC drove the research question and that is important
- SRPMIC has been very deliberate in determining how research should continue



- Research idea presented to TGen by SRPMIC Medical Director and Health staff based on clinical observations:
 - Significant number of patients diagnosed with renal cell carcinoma (RCC).
 - Unique research question due to incidence, gender and age.
- Joint study developed to evaluate the impact of RCC (kidney cancer) among community members. Study formally approved by Tribal Council.



- Research Plan and Research Collaboration Agreement signed in 2007 (also includes Material Transfer Agreement and Intellectual Property Agreement). TGen laboratory areas and staff blessed by Tribal elder.
- TGen consulted with SRPMIC Medical Director and Health Staff throughout the course of the study analyses and requested approvals as needed.
- Study data preliminarily discussed with the Medical Director and Health Staff. Additional options discussed and approved by Council to potentially continue study and validate findings.



Documents in Place

- Research Collaboration Agreement
- Material Transfer Agreement
- Intellectual Property Agreement
- Research Plan
- Informed Consent Form
- Hospital Transfer



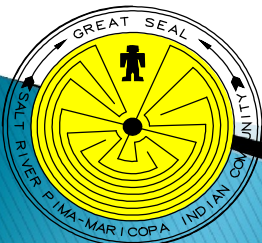
Research Collaboration Agreement

- Community and TGen are to perform collaborative research
- TGen can *only* perform research that is expressly authorized in Research Plan.
- Revenues from a Sole Invention and a Joint Invention will be shared equally by Community & TGen.
- All Results and Data will be jointly owned.
- Community can *terminate at any time* and Research Material will be returned to the Community on request.
- TGen may not disclose “Confidential Information” to third parties.
 - No distribution of Research Material (specimens) to third parties *without prior* Community and individual *authorization*.
- No publication by TGen *without prior written authorization* of Community.



Research Collaboration Agreement cont.

- Agreement provides for *a Limited Waiver of Sovereign Immunity* for the purposes of authorizing binding arbitration and judicial action before the U. S. District Court or Maricopa County Superior Court if the U.S. District Court lacks jurisdiction.
- Judicial actions are limited in scope and are only to encompass pre-arbitration injunctive relief, enforcement of a duty to arbitrate or enforcement of an arbitration award.



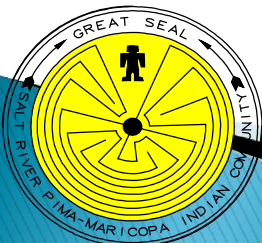
Material Transfer Agreement

- Research Material is owned by the Community.
- Upon completion of research, TGen obligated to return or dispose of Research Material as directed by Community.
- TGen can only use Research Material in strict conformance with the Research Collaboration Agreement.
 - Documents what Research Material is transferred to and accepted by TGen.



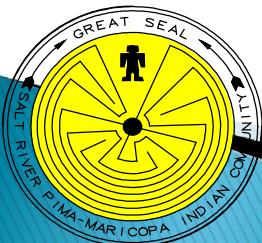
Research Plan

- Jointly Developed Scientific Protocol
- Outlines Technical Aspects of Study



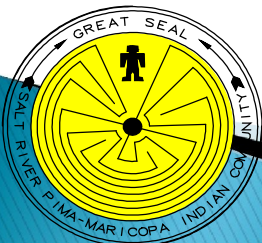
Informed Consent Form

- Form used to notify Community member of the risks and benefits of participation in the study
- Includes protections for:
 - Confidentiality
 - Biological Specimens
 - Participant Rights



Considerations

- True Partnership – Open Communication (respect and working to understand one another)
- TGen has kept the IRB paperwork up to date
- Very tight agreement, can impact research (Strong Heart)
- Staff Time to participate in the study
- Assuring that the contract is adhered to



Next Steps for SRPMIC

- Further Development of Research Commissions
- Continue to partner with TGen
 - Development of youth to be scientists
 - Articles in Community paper
 - Presenting information regarding various diseases, in particular diabetes

