STANDARD OPERATING PROCEDURE

GA-102 – Access and Use of Protected Health Information Preparatory to Research

1. **PURPOSE:**
   To define the procedures necessary to access and use UTRGV patient Protected Health Information (PHI) preparatory to research.

2. **SCOPE:**
   This SOP applies to UTRGV personnel who desire to access and use PHI preparatory to research (Investigator). Non-UTRGV personnel are permitted to use PHI preparatory to research only if credentialed through UTRGV research credentialing process.

3. **RESPONSIBLE INDIVIDUALS:**
   UTRGV employees interested in using or disclosing PHI preparatory to research are responsible for completing the required steps below. Prior to giving access to PHI, UTRGV employees must take responsible steps to ensure that the procedures stated herein have been followed by the requestor.

4. **RELATED TERMS AND DEFINITIONS:**

   Preparatory to Research
   Disclose
   Protected Health Information (PHI)

   Please reference the Standard Operating Procedure Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT:**
   Any UTRGV employee who desires to access or use PHI preparatory to research must follow the outlined procedures.

6. **PROCEDURES**:
   6.1 Obtaining the Data

   - The Investigator who desires to access or use PHI preparatory to research, must send an email to Decision Support at

utrgv_decisionsupportrequests@utrgv.onmicrosoft.com explaining the purpose of the request.

- A member of the Decision Support team will provide a link to the UT Health RGV Data Request Form.
- After completion and submission of the UT Health RGV Data Request Form, your request will be routed to the Office of Clinical Research (OCR). A member of the OCR team will reach out in a reasonable time frame, depending on the urgency of your request.

*Note – To help expedite approval of your request, submit your project to the IRB for a determination of whether your project is research BEFORE you request access to the data.

6.2 After the Approval

- No PHI will be removed from UTRGV (the Covered Entity) during the review of data. (Remove means the act of providing, transferring, or storing paper or electronic PHI off site of UTRGV premises. Examples include providing PHI on an external device for use offsite of UTRGV premises, emailing PHI to a non-UTRGV email account and/or storing electronic PHI on Google docs or other outside storage).
- The Investigator will retain the PHI in accordance with the policies on human subject research, only if needed as part of an approved research protocol from UTRGV. If no longer needed, the Investigator will destroy the PHI to ensure privacy and confidentiality of the PHI in accordance with UTRGV policies and procedures.
- The investigator or research staff may not use PHI obtained pursuant to this SOP to contact potential study subjects unless the Investigator receives IRB approval for the study protocol and that approval permits using patient information to contact about participation in the study.

7. REFERENCES

- https://www.utrgv.edu/irb/for-researchers/non-regulated-research/index.htm

8. FORMS OR ATTACHMENTS

UT Health RGV Data Request Form – will be sent upon request