Informed Consent Form

Title of Study:

The Prevalence and Characterization of Human Epidermal Growth Factor Receptor 2 (HER2) Expression Among Colorectal Cancer Patients in Sudan (2025)

Purpose of the Study:

You are invited to participate in a research study aimed at understanding the expression of HER2 in colorectal cancer and its relationship with disease characteristics.

Procedures:

This study will use archived tissue samples and medical record data. No additional procedures will be performed on you.

Risks and Benefits:

There are no direct risks to participants. The results of this study may help improve understanding and future management of colorectal cancer.

Confidentiality:

All information collected will be kept strictly confidential and used for research purposes only.

Voluntary Participation:

Your participation is voluntary, and you have the right to withdraw at any time without any effect on your medical care.

Consent Statement:

I have read and understood the information above and agree to participate in this study.

Participant Name: _____

Signature: _____

Date: _____

Appendix – 2:

Data Collection Checklist

A. Sociodemographic Data

- ☐ Age
- ☐ Sex
- ☐ Place of residence

B. Clinical Data

- ☐ Clinical presentation
- ☐ Tumor location (colon / rectum)
- ☐ Stage of disease (TNM classification, if available)

C. Histopathological Data

- ☐ Histological type
- ☐ Tumor grade
- ☐ Lymphovascular invasion
- ☐ Perineural invasion

D. Immunohistochemistry (HER2) Data

- ☐ HER2 staining status
- ☐ HER2 scoring (0, 1+, 2+, 3+)
- ☐ Final HER2 interpretation (negative / equivocal / positive)