**Annex I - Term of free and informed consent.**

**Title of this Project:** Quality of life of patients with inflammatory bowel disease

**Head Researcher:** Dr. Thais Karla Vivan, mentored by Dr. Carlos Henrique Marques

**Institution:** Regional Hospital of Mato Grosso do Sul - HRMS

**Contact phone number:** (67) 3378-2625

Name of the volunteer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Age: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legal representative (when applicable):

Legal representative ID:

You are being invited to participate, as a **volunteer**, in the study “Quality of life of patients with inflammatory bowel disease,” conducted by Dr. Thais Karla Vivian, Resident in General Surgery and mentored by Dr. Carlos Henrique.

This study aims to assess the quality of life of patients with inflammatory bowel disease by comparing the results between Crohn’s disease and ulcerative rectocolitis and by correlating quality of life data with sociodemographic and morbidity data.

You have been selected to participate thanks to your condition as a patient at the inflammatory bowel disease outpatient clinic of the regional hospital of Mato Grosso do Sul. You are not required to participate in the study. At any time, you may withdraw from participating and discontinue your consent. Your refusal, withdrawal from the study, or discontinuance of consent will not cause any harm to your treatment at the institution.

Participation in the study is not remunerated and will not involve expenses for participants.

Your participation in this study will consist of to answer, once only, to a questionnaire, which will be completed at the Regional Hospital of Mato Grosso do Sul.

The data obtained through this study will be confidential and will not be divulged at the individual level in order to ensure the confidentiality of your participation. The head researcher committed herself to making public in academic and scientific circles the results obtained in a consolidated form, without any identification of any participating volunteer.

You have the right to be kept up-to-date on all partial results of the study, or on results that are known to the researchers.

If you agree to participate in this study, please mark your signature at the end of this document, in two copies (one of them is yours, and the other one is for the head researcher/study coordinator).

Immediately or at any time, you may make use the following telephone numbers and institutional address of the head researcher and the Research Ethics Committee - CEP, where your concerns about the project and your participation in the study will be clarified. If required, contact the head researcher, Dr. Thais Karla Vivan, resident physician in General Surgery of the Regional Hospital of Mato Grosso do Sul, e-mail: thais.vivan@hotmail.com, Tel. (67) 3378-2625.

If you have any difficulty in contacting the head researcher or if you have any questions or concerns about the research ethics, please contact the Board of Education, Research and Institutional Quality, Research Ethics Commission, Regional Hospital of Mato Grosso do Sul - HRMS, Tel. (67) 3378-2909 and 3378-2766, Avenida Engenheiro Lutero Lopes, 36 - Conjunto Aero Rancho, Campo Grande - MS, CEP: 79084-180.

I believe I have been sufficiently informed about the information I have read, or that has been read to me, described in the **Quality of Life study of patients with inflammatory bowel disease**.

“I discussed with Dr. Thais Karla Vivan about my decision to participate in this study. It was clear to me what the purposes of the study were, the guarantees of confidentiality and of constant clarification. It was also clear that my participation is free of expenses and that I have guaranteed access to hospital treatment when necessary.

I voluntarily agree to participate in this study and may withdraw my consent at any time, before or during it, without penalty or damage, or loss of any benefit I may have acquired, or in my attendance at this Service.

I declare that I have obtained in an appropriate and voluntary manner the Free and Informed Consent of this patient or legal representative for his/her participation in this study.

Signature of the person in charge of the study

Date: \_\_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_\_\_.

I,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, legal representative of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, declare that I have been informed and agree to his/her participation as a volunteer in the research project described above.

I,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, ID #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, declare that I have been informed and agree to participate as a volunteer in the research project described above. **Or in the case of a volunteer under 18 years of age, illiterate, semi-illiterate, or with hearing or visual impairment.**

Campo Grande - MS, \_\_\_\_\_\_\_ (date)

Name and signature of the patient Name and signature of the responsible person

or legal representative for obtaining consente

Witness Witness

**Annex II – English version of the IBDQ.**

1. How often have you been evacuated in the last two weeks? Please indicate how often you have evacuated in the last two weeks by choosing one of the following options:
2. More frequently than ever
3. Extremely frequent
4. Very frequent
5. Moderate increase in frequency
6. Little increase
7. Small increase
8. Normal, with no increase in stool frequency
9. How often have you felt tired, drained, and exhausted in the last two weeks?
10. Always
11. Almost always
12. Often
13. A few times
14. Very few times
15. Rarely
16. Never

3-How often, in the last two weeks, did you feel frustrated, impatient, or restless?

1. Always
2. Almost always
3. Often
4. A few times
5. Quite a few times
6. Rarely
7. Never

4-How often in the last two weeks have you been unable to go to school or to work because of your bowel problem?

1. Always
2. Almost always
3. Often
4. A few times
5. Quite a few times
6. Rarely
7. Never
8. How often, in the last two weeks, have you had diarrhea?
9. Always
10. Almost always
11. Often
12. A few times
13. Quite a few times
14. Rarely
15. Never
16. In your opinion, what was your physical disposition in the last two weeks?
17. Absolutely no energy
18. Too little energy
19. A low level of energy
20. Some energy
21. A moderate amount of energy
22. A lot of energy
23. Full of energy
24. How often, in the last two weeks, have you been worried that you could need some surgery because of your bowel problem?
25. Always
26. Almost always
27. Often
28. A few times
29. Quite a few times
30. Rarely
31. Never
32. How often, in the last two weeks, did you have to delay or cancel a social commitment because of your bowel problem?
33. Always
34. Almost always
35. Often
36. A few times
37. Quite a few times
38. Rarely
39. Never
40. How often, in the last two weeks, did you have abdominal colic?
41. Always
42. Almost always
43. Often
44. A few times
45. Quite a few times
46. Rarely
47. Never
48. How often, in the last two weeks, did you feel bad?
49. Always
50. Almost always
51. Often
52. A few times
53. Quite a few times
54. Rarely
55. Never
56. How often, in the last two weeks, have you had problems for fear of not finding a toilet?
57. Always
58. Almost always
59. Often
60. A few times
61. Quite a few times
62. Rarely
63. Never
64. What difficulty did you have, in the last two weeks, to practicising sports or have a good time as you would like to have done because of your bowel problems?
65. The greatest difficulty: no way of doing these activities
66. Great difficulty
67. Moderate difficulty
68. Some difficulty
69. Little difficulty
70. Rarely, some difficulty
71. No difficulty
72. How often, in the last two weeks, have you been troubled by abdominal pain?
73. Always
74. Almost always
75. Often
76. A few times
77. Quite a few times
78. Rarely
79. Never
80. How often in the last two weeks have you had trouble getting a good night’s sleep or waking up at night? (Because of your bowel problem)
81. Always
82. Almost always
83. Often
84. A few times
85. Quite a few times
86. Rarely
87. Never
88. How often, in the last two weeks, did you feel depressed and lacking in courage?
89. Always
90. Almost always
91. Often
92. A few times
93. Quite a few times
94. Rarely
95. Never
96. How often, in the last two weeks, did you avoid going to places that did not have bathrooms (toilet) very close?
97. Always
98. Almost always
99. Often
100. A few times
101. Quite a few times
102. Rarely
103. Never
104. Generally speaking, in the last two weeks, what kind of problem did you have with the elimination of large amounts of gases?
105. The main problem
106. A big problem
107. An important problem
108. Some problem
109. Little problem
110. Rarely was a problem
111. No problem
112. Generally speaking, in the last two weeks, what kind of problem did you have to maintain your weight as you would like it to be?
113. The main problem
114. A big problem
115. An important problem
116. Some problem
117. Little problem
118. Rarely was a problem
119. No problem
120. Frequently, many patients with bowel problems are worried and anxious about their illness. This includes concerns about cancer, about never feeling better again, and about getting worse. How often, in the last two weeks, did you feel worried or anxious?
121. Always
122. Almost always
123. Often
124. A few times
125. Quite a few times
126. Rarely
127. Never
128. How long, in the last two weeks, did you feel that your belly was swollen?
129. Always
130. Almost always
131. Often
132. A few times
133. Quite a few times
134. Rarely
135. Never
136. How much time, in the last two weeks, did you feel restful and relaxed?
137. Never
138. Rarely
139. Quite a few times
140. A few times
141. Often
142. Almost always
143. Always
144. How long, in the last two weeks, have you had rectal bleeding problems with your bowel movements?
145. Always
146. Almost always
147. Often
148. A few times
149. Quite a few times
150. Rarely
151. Never
152. How long have you felt embarrassed over the past two weeks because of your bowel problem?
153. Always
154. Almost always
155. Often
156. A few times
157. Quite a few times
158. Rarely
159. Never
160. How long, in the last two weeks, have you been bothered by having to go to the toilet to evacuate, and failed despite your effort?
161. Always
162. Almost always
163. Often
164. A few times
165. Quite a few times
166. Rarely
167. Never
168. How long, in the last two weeks, did you feel like crying?
169. Always
170. Almost always
171. Often
172. A few times
173. Quite a few times
174. Rarely
175. Never
176. How long, in the last two weeks, have you been inconvenienced by accidentally evacuating your pants?
177. Always
178. Almost always
179. Often
180. A few times
181. Quite a few times
182. Rarely
183. Never
184. For how long have you felt anger over the last two weeks because of your bowel problem?
185. Always
186. Almost always
187. Often
188. A few times
189. Quite a few times
190. Rarely
191. Never
192. At what level has your sexual activity decreased in the last two weeks because of your bowel problem?
193. Absolutely no sex
194. Great limitation
195. Moderate limitation
196. Some limitation
197. Little limitation
198. Rarely limiting
199. Without limitation
200. How long, in the last two weeks, did you feel sick?
201. Always
202. Almost always
203. Often
204. A few times
205. Quite a few times
206. Rarely
207. Never
208. How long, in the last two weeks, did you feel uptight?
209. Always
210. Almost always
211. Often
212. A few times
213. Quite a few times
214. Rarely
215. Never
216. How long in the past two weeks did you experience a lack of understanding on the part of other people?
217. Always
218. Almost always
219. Often
220. A few times
221. Quite a few times
222. Rarely
223. Never
224. In the last two weeks, on what level did you feel satisfied, happy, or grateful about your personal life?
225. Very unsatisfied, unhappy most of the time
226. Generally dissatisfied, unhappy
227. A little dissatisfied, unhappy
228. Generally satisfied, grateful
229. Satisfied most of the time, happy
230. Very satisfied most of the time, happy
231. Extremely satisfied, could not be happier or grateful

# IBDQ SCORE

The questions that make up each domain are presented in an unordered way in the questionnaire so that biases in the answers are avoided. Each question within each of the domains checked consists of seven alternatives of answers. Each answer option is worth its own number in points, with 1 = worse quality of life and 7 = better quality of life, with the sum of the total points obtained in each domain. The simple sum of all domains will result in the total score obtained by the patient. The domains and their respective questions are listed below:

**1-Questions of the component “intestinal symptoms”:** 01, 05, 09, 13, 17, 20, 22,24, 26, 29 (Scores can vary from 10 to 70 points).

**2-Questions of the component “systemic symptoms”:** 02, 06, 10, 14, 18 (Scores can vary from 5 to 35 points)

**3-Questions of the component “social aspects”:** 04, 08, 12, 16, 28 (Scores can vary from 5 to 35 points).

**4-Questions of the component “emotional aspects”:** 03, 07, 11

**Annex III - Questionnaire 2.**

* 1. Age:
  2. Gender: ( ) male ( ) female
  3. Smoker? ( ) Yes ( ) No
  4. What is the disease? ( ) Ulcerative rectocolitis ( ) Crohn’s disease
  5. How many years since the diagnosis?

( ) <1 year

( ) 1-2 years

( ) 2-3 years

( ) >5 years

* 1. Currently which medication are you using?

( ) No medication

( ) Sulfasalazine, tablet

( ) Sulfasalazine, suppository

( ) Methotrexate

( ) Prednisone

( ) Azathioprine

( ) Anti TNF (ex: infliximab/adalimumab)

Other:

* 1. Have you had any surgery because of the disease?

( ) Yes

( ) No

* 1. Is the disease active?

( ) Yes

( ) No

( ) I don’t know

* 1. At any time did you run out of medication for lack of the drug in the Hospital?

( )Never

( ) Sometimes

( ) Often

( ) Always