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| Office for the Protectionof Research Subjects |        | Northwestern University750 North Lake Shore DriveSuite 700Chicago, Illinois 60611irb@northwestern.eduPhone 312-503-9338Fax 312-503-0555 |  |

2/15/2010

Dr.  [Gildasio De Oliveira JR.](https://www.vpn.northwestern.edu/eIRB/Personalization/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BMyProfile?Person=com.webridge.account.Person%5BOID%5B69F2FE2233E5C045913A6F1C1B63DDBB%5D%5D) M.D.
[Anesthesiology](https://www.vpn.northwestern.edu/eIRB/RMConsole/Organization/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BOrganizationDetails?detailView=true&Company=com.webridge.account.Party%5BOID%5B3316FDCBC239274CA70E554767172545%5D%5D)
211 east ohio street apt 618
Chicago  IL  60611
gildasiojunior@hotmail.com

**IRB Project Number:** STU00023482
**Project Title:**The effect of pre-operative transversus abdominis plane (TAP) block in the post-operative opioid consumption in morbid obese patients undergoing laparoscopic gastric bypass surgery: a prospective, randomized, blinded study
**Project Sites:**

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| [Northwestern Medical Faculty Foundation (NMFF)](https://www.vpn.northwestern.edu/eIRB/Doc/0/LBLI84VSFN7KN846U98VTCQE9C/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BfromString.html) |
| [Northwestern University (NU)](https://www.vpn.northwestern.edu/eIRB/Doc/0/LBLI84VSFN7KN846U98VTCQE9C/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BfromString.html) |
| [Northwestern Memorial Hospital (NMH)](https://www.vpn.northwestern.edu/eIRB/Doc/0/LBLI84VSFN7KN846U98VTCQE9C/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BfromString.html) |

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**Sponsor Information (Grant #, if applicable):**

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|   | There are no items to display |

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**Submission Considered:**New Submission **Submission Number:**STU00023482
**Review Type:** Full IRB Review
**Meeting Date** (for Full Review) 2/12/2010
**Panel:**Panel C
**Status:**APPROVED **Approval Period:**(2/12/2010 - 2/11/2011)

Dear Dr. De Oliveira JR.,

The IRB considered and approved your submission referenced above through 2/11/2011 . As Principal Investigator (P.I.), you have ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of human subjects.  You are required to comply with all NU policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

* Not changing the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
* Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
* Promptly reporting unanticipated problems involving risks to subjects or others, or promptly reportable non-compliance in accordance with IRB guidelines.
* Submit a continuing review application 45 days prior to the expiration of IRB approval. If IRB re-approval is not obtained by the end of the approval period indicated above, all research related activities must stop and no new subjects may be enrolled.

**IRB approval includes the following:**

**Written Consent Form/Consent Form and Authorization for Research:**

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| Name |
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| [Consent](https://www.vpn.northwestern.edu/eIRB/Doc/0/QDMV2E2JGVD4397R10T7MRDHB6/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BClean%20Gastric%20consent%20revised%20pre%20review%2002.10.2010.doc) |

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**Investigator Brochure - approved drug for an approved use:**

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| set of Document | 12/11/09 | 12/11/09 | [ID00001130](https://www.vpn.northwestern.edu/eIRB/Rooms/DisplayPages/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BLayoutInitial?Container=com.webridge.entity.Entity%5bOID%5bF5DD6568AEDD844985A11149E0A77A35%5d%5d&Tab2=com.webridge.entity.Entity%5bOID%5b871B369A5D743E4485748A898700948E%5d%5d) | Ropivacaine |
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**Protocol Document:**

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| Name |
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| [Data Collection Form](https://www.vpn.northwestern.edu/eIRB/Doc/0/DB9T0GN5AP0479CRUEC5Q1O6E9/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BData%20collection%20form%2012.21.09.docx) |
| [Log Book Participants](https://www.vpn.northwestern.edu/eIRB/Doc/0/5LF8C5TPKN64FABLO489C05GA7/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BCopy%20of%20Log%2520Book%2520Participants.xls) |
| [Protocol](https://www.vpn.northwestern.edu/eIRB/Doc/0/4RPR8GRC3ETKJ8LDAB0EADFM06/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BTAP%20gastric%20protocol%20revised%2002.10.2010.doc) |
| [Sonosite Brochure](https://www.vpn.northwestern.edu/eIRB/Doc/0/NKAKFNGSS994H8QLDR5B46DP40/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2Bsonosite_180plus_brochure.pdf) |

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**NMH Protocol Review Form:**

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| Name | Description | Modified |
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| [Gastric](https://www.vpn.northwestern.edu/eIRB/Doc/0/E4FH0I5B6PP4VAOJRLE86UHG8E/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BHospital%20office%20of%20research%20protocol%20form%20Gastric%20tap%20block%2012.16.doc) |   | 2/10/2010 10:37 AM |

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**Survey/Questionnaires:**

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| Name |
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| [MQOR40](https://www.vpn.northwestern.edu/eIRB/Doc/0/NGFR18G3C4BKVBCQLL1DR0F8C6/%2CDanaInfo%3D.awxyCinxiHwy25u-t8-w-7U00G%2CSSL%2BModified_Quality_of_Recovery_Survey%5B1%5D.doc) |

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| For more information regarding OPRS submissions and guidelines, please consult [http://www.northwestern.edu/research/OPRS/irb](https://www.vpn.northwestern.edu/research/OPRS/%2CDanaInfo%3D.awxyCrtx0p5o35r52PvvB%2Birb).This Institution has an approved Federalwide Assurance with the Department of Health and Human Services: FWA00001549. |  |