



Bronson Methodist Hospital Institutional Review Board (IRB)

IRB APPLICATION INSTRUCTIONS

- The type of review (Full, Expedited, of Exempt) will be determined by the IRB chairperson.
- Full Review will require the submission of 1 unstapled original of all required documents, this will have an internal review conducted within 48 hours, after which time the IRB office will contact you. If there are no immediate changes requested before review by the IRB committee then 14 (fourteen) 2-sided, stapled copies will be requested. If there are immediate changes requested before review by the IRB Committee then the IRB office will relay these changes to you to be made and then 14 (fourteen) 2-sided, stapled copies of the revised protocol will be requested.
- Expedited Review will require the submission of 1 unstapled original of required documents, plus one 2-sided stapled copies
- Submission deadline and meeting dates: The IRB meets the 2nd Thursday of each month. Submissions deadlines are located on-line at <http://www.bronsonhealth.com/Research/BronsonIRB/page3899.html.html> or by contacting the IRB office by phone at (269)-341-7898 or by e-mail at wardk@bronsonhg.org.

IRB REQUIRED DOCUMENTS : All forms are available on-line at <http://www.bronsonhealth.com/Research/BronsonIRB/page3899.html.html>

- Cover letter** addressed to James Carter, MD
(<http://www.bronsonhealth.com/Research/BronsonIRB/IRB%20Submission%20Cover%20Letter%202007.doc>.doc)
- Completed **Application for Institutional Review Board** (5 pages)
- Copy of the **Curriculum Vitae** for the Principal Investigator (PI) and each Co-Investigators. Each CV needs to be signed and dated.
- Completed and signed **Conflict of Interest form** by PI and each Co-Investigators. Note: For a pharmaceutical sponsored study, a copy of the signed financial disclosure may be substituted for the ‘Conflict of Interest’ for the Principal Investigator and Co-Investigators.
- Signed **Investigator Agreement** (2 pages) for the Principal Investigator and each Co-Investigator
–or– A copy of the signed FDA 1572 form for protocols involving an investigational drug under an IND.
- Evidence of education** regarding the protection of human subjects for the Principal Investigator, all co-investigators and all members of the research team. Suggested training: The National Institute of Health has developed a computer-based training module on protection of human subjects. This training module can be found at <http://phrp.nihtraining.com/users/login.php> . *Complete all sections.* At the end of the tutorial, print a completion certificate. Submit a copy of the certificate along with your application (maintain original for future use).
- Submit the **complete research protocol**. (See ‘Guidelines for Writing Research Protocols’)
- Bibliography** of relevant research.



- ❑ **Consent(s) forms or participant cover letter(s)**. (See 'Informed Consent Template and Checklist for Creating Informed Consent').
- ❑ **Assent form** (if subjects are under 18 years of age).
- ❑ If applicable, **Waiver of Informed Consent and Authorization** (See 'Does HIPAA Apply to My Research')
- ❑ **Copy of instrumentation** to carry out the study (Surveys, data collection forms etc).
- ❑ **Copy of any materials that will be used to recruit** research volunteers (i.e. letter, flyer, public advertisement, etc., include PI's name and name of protocol on this material).
- ❑ **Investigator Brochure** (if applicable).
- ❑ **Flesch-Kincaid Reading Level** for consents and recruitment materials (FDA recommends 8th grade or lower).

HUMANITARIAN USE DEVICES (HUD) REQUIRED DOCUMENTS :

The Bronson IRB has the discretion to determine the conditions of HUD use. The IRB may approve the use of the device in general, in a specific number of patients, only under specific circumstances, etc. The Bronson IRB may limit the use of the HUD based on any criteria that it deems appropriate.

- ❑ **Cover letter** addressed to James Carter, MD (See 'Sample Cover Letter')
- ❑ **Summary** from the device sponsor that documents the following:
 - Generic and trade name of the device
 - The FDA HDE number (this is a six-digit number, preceded by the letter 'H')
 - The date of HUD designation
 - Indications for use of the device
 - A description of the device
 - Contraindications, warnings, and precautions for use of the device
 - Adverse effects of the device on health
 - Alternative practices and procedures
 - Marketing history
 - Summary of studies using the device
- ❑ **Signed statement** from the local user that the HUD is not being used as part of a research project or clinical investigation designed to collect data to support an FDA pre-market approval application.
- ❑ Completed **Application for Institutional Review Board** (4 pages)
- ❑ Copy of the **Curriculum Vitae** for the Principal Investigator (PI) and each Co-Investigators. Each CV needs to be signed and dated.
- ❑ Completed and signed **Conflict of Interest form** by PI and each Co-Investigators. Note: For a pharmaceutical sponsored study, a copy of the signed financial disclosure may be substituted for the 'Conflict of Interest' for the Principal Investigator and Co-Investigators.
- ❑ Signed **Investigator Agreement** (2 pages) for the Principal Investigator and each Co-Investigator



–or– A copy of the signed FDA 1572 form for protocols involving an investigational drug under an IND.

- ❑ **Evidence of education** regarding the protection of human subjects for the Principal Investigator, all co-investigators and all members of the research team. Suggested training: The National Institute of Health has developed a computer-based training module on protection of human subjects. This training module can be found at <http://phrp.nihtraining.com/users/login.php> . *Complete all sections.* At the end of the tutorial, print a completion certificate. Submit a copy of the certificate along with your application (maintain original for future use).

- ❑ **If applicable, Consent(s) forms or participant cover letter(s).** (See ‘Informed Consent Template and Checklist for Creating Informed Consent’).

- ❑ **If applicable, Assent form** (if subjects are under 18 years of age).

- ❑ **Flesch-Kincaid Reading Level** for consents and recruitment materials (FDA recommends 8th grade or lower).

Mail application to: Kyra Ward
Bronson Methodist Hospital
301 John Street, Box 92
Kalamazoo, MI 49007

- or -

Deliver to: Bronson Healthcare Group
301 John St. (Ground Level), Kalamazoo
Questions? Contact Kyra Ward, 269-341-7898
Email: wardk@bronsonhg.org