

## MEET YOUR TEAM!

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# IRBMED

REGULATORY TEAM  
WORKING FOR YOU!



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## DEPARTMENTS WE SERVE

IRBMED administrative staff manage incoming applications by Principal Investigator's Department and subject matter of the protocol.

**The following are the departments we serve:**

1. Allergy
2. Cardiology, / Cardiac Electrophysiology / Cardio-Thoracic Surgery
3. Endocrinology / Metabolism / Diabetes
4. Genetics / Microbiology
5. Hypertension / Vascular Surgery
6. Infectious Disease
7. Nephrology
8. Pulmonology
9. Pharmacokinetics / Pharmacy
10. Radiology Devices
11. Rheumatology
12. Transplant: Heart / Lung / Kidney / Liver

## EXEMPT STUDIES: 45 CFR 46.101 (B) (MOST COMMON GRANTED BY IRBMED)

Exemption 4: Existing data documents, records, specimens, if these are publicly available or if the information is recorded in such a manner that subjects cannot be identified directly or linked to subjects (paraphrased)

## EMERGENCY USE: 21 CFR 56.102 (D), 104 ( C ) / 45 CFR 46.116 (F)

A life-threatening situation exists in which no standard acceptable treatment is available and there is not sufficient time to convene a quorum for full-board IRB review and approval.

Call and email the IRBMED office as soon as the decision to use an unapproved test article is made, prior to the treatment or procedure if at all possible. After hours, weekends/holidays, send email and ask the UMHS operator (734/936-6267) to page the IRBMED chair on call. File a formal report of the emergency use in eResearch within **5 days** of the use. Indicate in section 1.12 of the application whether the report is for an investigational drug/biologic or investigational device.



## COMPASSIONATE USE (AS IRBMED USES IT)

Usually when an investigational drug or device is being used outside the setting of a clinical trial. The use is for a small number of extremely ill patients when standard therapy is ineffective.

A sub-protocol has been established by the Sponsor and the FDA has approved continued accrual. Data can be used as part of the research study.

## HUMANITARIAN USE DEVICE:

[HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDRH/CFDOCS/CFHDE/HDEINFORMATION.CFM](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hdeinformation.cfm)

An HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the USA..

Once initial approval is received IRBMED does not need to review and approve on label individual uses of an HUD. Continuation Reporting annually is a requirement for use of these devices. 21 CFR 56.109 (f).

IRBMED encourages Faculty to serve on the Board. Terms are for three years. Contact Jan Hewett Director, 734-647-7615 [jhewett@umich.edu](mailto:jhewett@umich.edu)