

MEET YOUR B1 TEAM!



BELINDA ADAMSON, BS, MED, CLS, CCRC, CIP

Senior Associate Regulatory Analyst (SARA)

aske@med.umich.edu

734-615-5072

CAROL HUTSKO, BBA

Junior Associate Regulatory Analyst (JARA)

chutsko@medumich.edu

phone: 734-647-2089

ELLEN LACHANCE, AAS

Assistant Regulatory Analyst (ARA)

emlac@med.umich.edu

phone: 734-615-5074

WHAT IS STACKING?

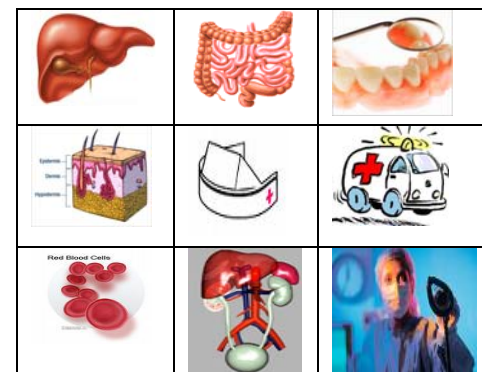
Stacking refers to ordering the versions of documents uploaded into eResearch

When a document already exists in eResearch **EDIT** the document. **NEVER** delete a previously approved document.

When a document is being uploaded for the first time into eResearch **ADD** the document.

IRBMED

**THE B1
REGULATORY TEAM
WORKING FOR YOU!**



IRBMED

Argus I Bldg
517 W. Williams St
Ann Arbor, MI 48103-4943

Phone (734) 763-4768

Fax (734) 615-5399

<http://www.med.umich.edu/irbmed>



**SAFEGUARDING RIGHTS OF
HUMAN SUBJECTS**



DEPARTMENTS WE SERVE

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

The following are the departments we serve:

- Anesthesiology
- Dentistry
- Dermatology
- Emergency Medicine
- Gastroenterology
- Hepatic
- Hematology
- Nursing
- Urology

EXCEPTION FROM INFORMED CONSENT FOR STUDIES CONDUCTED FOR EMERGENCY SETTINGS

FDA regulation 21 CFR 50.24 provides a narrow exception to the requirement for informed consent from each human subject, or his or her legally authorized representative, prior to initiation of an experimental intervention. The exception would apply to a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized person to represent them. The intent of the new regulation is to allow research on life-threatening conditions for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent, while establishing additional protections to provide for safe and ethical studies.

If you wish to use this regulation, there are additional federal requirements beyond the regular IRB review process. You **MUST** contact an IRB chair or IRB director first.

EXEMPT STUDIES

EXEMPTION #1 OF THE 45 CFR 46.101(B):

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

EXEMPTION #2 OF THE 45 CFR 46.101(B):

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

EXEMPTION #4 OF THE 45 CFR 46.101(B):

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

