Lifespan

Frequently Asked Questions – IRB

1. *What is the IRB?*

The Institutional Review Board (IRB) is a committee made up of physicians, scientists and community members who ensure that research involving human research subjects is well planned and ethical. See slide presentation on IRBs at: http://www.lifespan.org/research/irb/docs/irbtraining/whatistheroleoftheirb.ppt

2. *What needs IRB review?*

All research that involves human subjects must be reviewed by the IRB.

Research is defined as "*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*".

"Human subject means a living individual about whom an investigator conducting research obtains data through intervention with the individual, or identifiable information."

All data collected by an interaction or intervention with human subjects must be approved by the IRB BEFORE the project begins. This applies to ALL data collection involving human subjects conducted at Lifespan or by Lifespan agents, including data collection in the humanities and behavioral and social sciences, whether the research is externally funded or not.

Please refer to OHRP decision trees if you are not sure if your project meets the definition of human subject research.
http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm

3. *How do I submit an IRB Application?*

Instructions, forms and deadlines for IRB submission are located on the IRB webpage, http://www.lifespan.org/research/.

Briefly, the research protocol and all applicable IRB forms (e.g. consent, assent, specimen banking, etc) are to be downloaded from the website. The complete, collated application, along with the appropriate number of copies for the type of review, are to be delivered to the Research Review Committee Office in Aldrich 5. Deadlines for full board review are posted on the website. Expedited and Exempt applications do not have a deadline and are processed on a rolling basis.

4. *What forms do I need and how do I find them?*

The checklist for the required forms is posted on the IRB webpage, http://www.lifespan.org/research/, under the heading for instructions.

IRB forms are located on the IRB webpage, under forms.

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5. How do I know if my project qualifies for exempt or expedited review?

http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm
See Charts 3-8.
Federal Regulations describe the types of research that may qualify for exempt or expedited review. The types of research that generally qualify for exempt or expedited review present no more than minimal risk. The IRB may choose to apply a stricter standard and require full board review for some projects that would appear to qualify for expedited /exempt review.

A Hyperlink to the Federal regulations is included on the IRB webpage under Instructions, http://www.lifespan.org/research/.

6. What is a data safety monitoring plan and why do I need one?

The IRB is responsible for ensuring that protocols contain "*adequate provision for monitoring data collected to ensure the safety of subjects*".
When submitting a research application for IRB review, the research plan (protocol) should describe the basic parameters of the data monitoring process. Please note, this is not to be confused with the procedure for reporting serious reportable unanticipated problems/adverse events (SAEs) to the sponsor or FDA.

- Keep in mind every study should have some kind of data safety monitoring plan (DSMP). As the risk of the study increases the data safety monitoring plan should be more detailed and perhaps build to a data safety monitoring board (DSMB). The IRB should be told whether the plan is to assign the responsibility for data and safety monitoring to an individual investigator, the sponsor, or a DSMB, also called a data monitoring committee (DMC- FDA wording). If the study sponsor will be responsible for data and safety monitoring, the research plan should describe the number of people who will be responsible for this task and their qualifications to function in this capacity.
- The research plan should describe the planned frequency of data analysis (per time basis, per subject basis or in response to specific events).
- The research plan should give a description of stopping rules regarding potential outcomes of the study that are likely to have a major impact on the rights or welfare of research participants.

More information regarding data safety monitoring can be found at;

http://grants.nih.gov/grants/guide/notice-files/not98-084.html

http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

http://www.fda.gov/CBER/gdlns/clintrialdmc.pdf

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7. How long does expedited review take?

Expedited review does not necessarily mean faster. New applications and revision requests that qualify for expedited review, in accordance with federal regulations, typically require 10-14 days from the time of receipt on the Research Review Committee Office. Additional time may be required if clarifications or revisions are requested by the reviewer.

8. Do I need Human Subjects Protection Certification/training?

All personnel who interact with human subjects, or their identifiable data, are required to be certified in human subject protections. Human subject Protection Certification is achieved by completing an on-line course through CitiProgram (http://www.citiprogram.org). Instructions are posted on the IRB webpage under Mandatory Education.

9. Now that my study is approved, what do I have to do?

Investigators are responsible for reporting adverse events to the IRB, in a timely manner. Changes cannot be instituted in a protocol until they have been reviewed and approved by the IRB. Projects are approved for a period of time up to one year from the initial IRB review date. Investigators are required to provide a progress report requesting approval for continuation before IRB approval expires. You will be notified when your progress report is due. Please complete the progress report form and submit it on or before the deadline date provided. Progress reports can be located on the webpage at: http://www.lifespan.org/research/irb/docs/irbforms/irbotherforms/cont.reviewreport.doc

10. What do I have to report to the IRB?

Investigators must promptly report any problems encountered with the protocol, any and all unanticipated problems/adverse events that involve risk to subjects or others. Federal regulations require organizations to have written policies and procedures to ensure the prompt reporting of unanticipated problems involving risks to subjects or others to the IRB, appropriate institutional officials, and regulatory agencies. *See Section 8 of the Lifespan Policy and Procedure Manual for applicable definitions, policy and, procedure. (Add link)*
See the Unanticipated Problems/Adverse event reporting instructions and forms for reporting details. (Add link)

11. How do I close my study when the research is complete?

Progress report reminders are sent to principal investigators approximately two months before expiration of IRB approval. The progress report form should be completed as indicated for terminating studies. If a study is terminating well before the time when a progress report would be sent, a progress report form can be downloaded from the IRB website. Please note, for sponsored projects (e.g.

clinical trials), you should not terminate IRB review until the sponsor/study monitor completes a close-out visit.
Progress reports can be located on the webpage at:
http://www.lifespan.org/research/irb/docs/irbforms/irbotherforms/cont.reviewreport.doc

12. When should a QA Study or a QI/QA Project be submitted to the IRB for Review?

Does the QI/QA Project meet the definition of Research?
Does the QI/QA Project involve Human Subjects as defined by Research Regulations?

DHHS Definitions: 45 CFR 46.102(d), (f)
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (i.e., knowledge obtained in the study may be disseminated/ shared with or applied beyond the actual study population or institution where the study was conducted).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

FDA Definitions: 21 CFR 50.3 (c), (g)
Clinical investigation means any experiment that involves a test article and one or more human subjects and that is subject to requirements of the Food and Drug Administration or as part of an application for a research or marketing permit.

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

If the proposed project meets the definitions above, then submit an application to the IRB. If you are unsure as to whether or not the project meets, or does not meet, the definitions above, then use the following checklist for guidance.
http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm