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Investigator Checklist: New Projects

For all non-exempt human subjects research that must be reviewed by an IRB

This checklist is a guide to complete the submission process, not a required submission document. Incomplete submissions will be unlocked and increase processing time.

Before you begin:

1. The activity is research.
2. The research involves human subjects.
3. If the research is eligible for exemption, all New Project documents are required, as outlined below.

Before you submit your application to the IRB, please make sure that you have included all appropriate forms. **Required forms vary by the type of research.** Additional forms/documents may need to be required, as outlined below.

Research Application Part 1 is an on-line form. Designer > Start a Wizard > Lifespan – Research Application Part 1 – Human Subject Studies. The remaining documents in this checklist must be downloaded from the Forms & Templates Library or provided by the investigator.

QUICK LIST OF DOCUMENTS

- ☐ Research Application Part 1 (on-line document)
- ☐ Research Application Part 2 (Retrospective charts reviews or Prospective research)
- ☐ Research Plan, Sponsor's Protocol
- ☐ Informed Consent or Waiver of Consent Forms Appendix (see below)
- ☐ HIPAA Privacy Rule Forms (if applicable)
- ☐ Appendix 1 (Children, Prisoners, Pregnant Women, Impaired-Decision Making etc)
- ☐ Appendix 2 (Waiver of Consent, Documentation of Consent, Surrogate Consent)
- ☐ Appendix 3 (DoD funded research)
- ☐ Data Abstraction Tool
- ☐ Study Instruments -Questionnaires, tools, measures, surveys, etc.
- ☐ Advertisements, flyers, brochures
- ☐ Investigator Brochure (IB) - For investigational drugs only
- ☐ IFU (Instructions for Use) - For Investigational devices.
- ☐ Nursing Service-Approval form
- ☐ Letter(s) of Cooperation- Required if other departments provide services or clinical care, ex: pharmacy, pathology.
- ☐ Package Signatures: PI and Department Chairperson

See detailed list of required actions and documents below.

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START HERE

- ☐ The initial package must be **signed** by both the PI and the Department Chairperson.
- ☐ Sponsor in Project Profile matches sponsor in Research Application Part 1, and consent form, if applicable.
- ☐ All documents need a **version date** and **page numbers**, when possible

PI/KSP Requirements

- ☐ HIPAA Security Certification within the **last year** (PI Only)
- ☐ CITI Human Subjects Protection Certification/Re-Certification within the past **three years**.

REQUIRED ACTIONS AND DOCUMENTS

1. CREATE A NEW PROJECT

- ☐ Click to add package description or notes (optional but recommended)
- ☐ Indicate the funding source in Project Profile: **Sponsor** or Department name is required.
  This is done by clicking the "Project Overview" tab off to the left hand side, then clicking the yellow "Edit" button under the Project Title.

2. DESIGNER – Start a Wizard

- ☐ **Lifespan – Research Application Part 1 – Human Subject Studies**
  Research Application Part 1 is an online document in IRBNet. Click "Start a Wizard" in the Designer.
  - * All personnel must have certified within the last three years in HSP training, and the most recent date should be entered.
  - * The project funding section must have a funding type listed, and a cost center or "pending" indicated.
    Note: A department funded study requires a cost center. Grant funded studies require a Grant Recipient. Please do not list your sponsor as "None" or leave this field blank.
  - * Indicate if any personnel listed have a COI; if so, please notify the Office of Research Administration at 401-444-5113. Please refer to the Office of Research Administration website to determine COI based on the definitions indicated in this policy.

Download Forms, Templates and References from the applicable Lifespan Forms and Templates library
Select a Library: Lifespan – Rhode Island Hospital IRB or Lifespan – The Miriam Hospital IRB
Select a Document: [DOCUMENT NAME]

3. DESIGNER – Download Required Forms

- ☐ **Application Part 2 (FORM)** for retrospective chart reviews OR for prospective research
  - * For studies that may be greater than minimal risk, please be sure a DSMP is indicated appropriately in Section VI.

ADDITIONAL FORMS AND DOCUMENTS

The following documents may or may not apply depending on the type of research.

Informed Consent

- ☐ Adult – for subjects 18 years or older
- ☐ Minor – for parental permission of subjects less than 18 years
- ☐ Assent - Recommended in some types of studies for use with children ages 8-17.
- ☐ *Additional informed consent templates available in the F&T Library*

Appendix 2 – Informed Consent Requirements

- ☐ Surrogate Consent – Appendix 2, Section A if the study involves Decisionally Impaired
- ☐ Waiver of Consent – Appendix 2, Section B if consent will not be obtained
- ☐ Waiver of Consent For (Documentation of consent) – Appendix 2, Section C if the study involves phone screening, surveys etc
- ☐ Waiver of Consent Form (if not seeking signed consent), include an informational letter.

HIPAA

- ☐ Prep to Research - The study involves reviewing records to determine eligibility prior to consent and authorization
- ☐ Waiver of Authorization - This form must be completed by researchers having and recording access to protected health information (PHI) for research without written authorization (consent) from the research subject.
- ☐ Decedent Data Review - This form must be completed by researchers who wish to record PHI on decedent's protected health information (PHI).
- ☐ Accounting of disclosures – Required if PHI will be disclosed to non-Lifespan employee or outside the institution.

Investigational drugs and medical devices

- ☐ Investigator Brochure (IB) or package insert
- ☐ IFU (Instructions for Use) - For Investigational devices.
- ☐ Nursing Service-Approval form (Nursing Approval Investigational Devices/Drugs in FORMS and TEMPLATES) - Required in order to administer Investigational drugs/devices to Lifespan patients. Be sure to obtain the Nursing Director's signature.
- ☐ If your study involves an investigational drug or device, provide documentation of the IND/IDE # provided by the FDA.

Appendix 1 – Subject Populations Requirements

- ☐ Inclusion of Children: include Application Appendix 1A-VulPop-Children.
- ☐ Inclusion of Prisoners: include Application Appendix 1B-VulPop-Prisoners.
- ☐ Inclusion of Pregnant Women/fetuses/neonates: include Application Appendix 1C- VulPop-PregWomen-Fetuses.

☐ Inclusion of Decisionally or Cognitively Impaired: include Application Appendix 1D- VulPop-Decisionally Impaired.

☐ Inclusion of Children: include Application Appendix 1A-VulPop-Children.

Appendix - Department of Defense Requirements

☐ Application Appendix 3-For DoD Funded Studies Form - (Required for studies for which the Department of Defense is the Sponsor).

Additional Steps

☐ Radiation Exposure

If the study includes x-rays, CT scans, or other imaging radiation therapy which involves more exposure to radiation than patients would be exposed to compared to standard of care, please contact Michael Oumano, Radiation Safety Officer at Moumano@lifespan.org for language to be included in the consent form.

REQUIRED DOCUMENTS PROVIDED BY INVESTIGATOR (as applicable)

☐ **Biographical sketch or CV** for the Principal Investigator
CV should be up-to-do with current medical license

☐ **Research Plan, Protocol** with references

☐ Study Instruments - Questionnaires, tools, measures, surveys, etc

☐ Letter(s) of Cooperation - Required if other departments provide services or clinical care, ex: pharmacy, pathology.

☐ Data abstraction tool(s), or list of data fields to be recorded

☐ Recruitment Materials such as advertisements, flyers, brochures, etc.

If you are using online advertising such as social media, Facebook, Twitter, texting, etc. to help promote your study through social media, please contact Nancy Jean, Senior Media Relations Officer at njean@lifespan.org.

☐ Any other study related document that would be relevant to IRB review

4. DESIGNER – Attach New Document

☐ Attached all applicable documents as referenced above

5. SIGN THIS PACKAGE

☐ New Project package must be **signed** by the PI.

6. SUBMIT THIS PACKAGE

☐ Submission Type: New Project

For assistance, please contact the Lifespan Research Protection Office. See RPO Directory in the Forms and Templates Library.

What happens next?

1. IRB Coordinator conducts a pre-review of the submission
2. Incomplete submissions will be unlocked to allow for revisions.
3. Complete submissions will be assigned for review. Click on “Reviews” to check the status of your submission.