Review of New IRB Policies

OHR-1 signature requirements

- The OHR-1 must be signed by the **Principal Investigator**, and the **Chair** and **Business Administrator** of his/her department. All other investigators and research personnel on the study must be listed. Signatures for these personnel are <u>not required</u>. However, if personnel from a department other than that of the PI are involved in the study, the chair and business administrator of that department also must sign below.

OHR-1 signature requirements

5. SIGNATURES:

The OHR-1 must be signed by the **Principal Investigator**, and the **Chair** and **Business Administrator** of his/her department. All other investigators and research personnel on the study must be listed below. Signatures for these personnel are not required. However, if personnel from a department other than that of the PI are involved in the study, the chair and business administrator of that department also must sign below.

- The **Principal Investigator** agrees to accept responsibility for the conduct of the project according to the tenets of Good Clinical Practice (DHSP Policy GA 124, "Good Clinical Practice for Investigators") and to provide the required progress reports if a grant/contract results from application/proposal.
- **Department Chairs** certify that the project meets Departmental standards with respect to scientific validity and that the project is consistent with Departmental goals.
- **Administrators** certify that the project meets applicable federal fiduciary requirements.

Principal Investigator	**Departmental Chair**	**Business Administrator**
Sign above and print name here	Sign above and print name here	Sign above and print name here

Co-Investigators/Key Personnel (List names below – signatures not req'd)	**Departmental Chair** (Signature required if department differs from that of PI)	**Business Administrator** (Signature required if department differs from that of PI)

Subject initial/date requirement

- The Office of Human Research has eliminated the requirement for subjects to initial and date each page of the OHR-8 consent form.
- For currently active studies, no amendment is necessary to remove this section from the consent form. As of this policy change, researchers can simply ignore the section and the requirement.
- At the time of continuing review, if the consent form needs re-stamping, the subject initial/date section should be removed from the footer.

Subject initial/date requirement

- Note that the amendment policy (IC 702) does require that when the IRB has determined that subjects should be re-consented with a revised consent form, they initial & date revised pages and sign the signature page.

- (Once initial & date lines have been removed from the OHR-8 template, subjects can initial & date anywhere in the margin of revised pages.)

Guidance for Staffing of Personnel on Research Studies

- Oftentimes in inpatient clinical research there is a need for continuous staff coverage to perform study-related procedures such as administering study drug, and performing blood draws and study assessments.
- Whether staff are Jefferson employees, volunteers, or hired from an agency, the following guidelines should be applied to determine whether or not the staff should be considered research personnel and listed on the OHR-1 for the purposes of IRB oversight:

Guidance for Staffing of Personnel on Research Studies

Activities considered research	Activities not considered research
1. Administering non-FDA approved study drugs not provided by the Investigational Drug Service (IDS)	1. Administering study drugs provided by the IDS, and as per order of the principal or co-investigator.
2. Performing study-mandated, research-specific assessments	2. Performing study-related procedures that are within standard scope of clinical practice, e.g., blood draws
3. Collecting PHI for research purposes and that is not otherwise routinely collected for clinical care	3. Preparing & submitting IRB paperwork
4. Reporting SAEs &UAPs	4. Handling de-identified patient data
5. Making independent, protocol-related decisions	5. Interacting with a patient on a clinical basis
6. Consenting subjects	6. Informing patients about a study or providing them with recruitment materials
7. Independently interacting with subjects to collect research data	7. Following direct orders of principal investigator or co-investigator

Guidance for Staffing of Personnel on Research Studies

- Personnel that are conducting **activities considered research** fall under IRB oversight and thus must be listed as research personnel on the OHR-1 and must complete appropriate CITI training and submit conflict of interest disclosure to the Office of University Counsel prior to involvement in the research.