Procedure Statement
The Perelman School of Medicine (PSOM) requires research team members, inclusive of faculty, staff, contractors, and students, who are making a direct and significant contribution to data on clinical research protocols conducted under an Investigational New Drug (IND) to be listed as sub-investigators on the Form FDA 1572 Statement of Investigator. For Device trials not associated with an IND, the form 1572 does not apply and an investigator agreement must be documented as clearly outlined in 21 Code of Federal Regulations 812.43.

History
The Form FDA 1572 (Statement of Investigator) is a signed statement completed and signed by the Principal Investigator. By signing the Form FDA 1572, the Principal Investigator attests that he/she will comply with the FDA regulations related to the conduct of the clinical investigation being studied under the IND. Section 6 of the Form FDA 1572 requires a list of sub-investigators participating in the conduct of the research under the Investigator. It is the responsibility of the Principal Investigator to ensure that his/her sub-investigators engaged in the research are qualified and trained to perform the study related activities assigned to them.

Purpose
The purpose of this policy is to assist the PSOM research community in determining which members of the research team who perform activities on a clinical trial need to be listed on Form FDA 1572 as sub-investigators.

Who Should Know This Policy
Any research team, faculty or staff member engaged in research being conducted under an IND.
Definitions

Sub-Investigator: any investigative team member who makes a direct and significant contribution to the data. Sub-investigators may include but are not limited to physicians, medical residents, research nurse practitioners, registered nurses and research coordinators. Individuals not likely to be a sub-investigator per this definition include hospital staff, including clinical nurses, residents or office workers who provide ancillary or intermediate care as part of their normal duties, project managers, regulatory coordinators, pharmacists, and individuals who have an occasional role in research, such as phlebotomists or on-call physicians. Where larger laboratories, nursing units, with extensive staff are utilized, only the lead nurse or unit lead performing the work for the study are required to be listed on the 1572. Additional staff should be listed only if the responsibility to perform direct and significant study related activities is specialized within the unit. For details see below:

Direct and Significant study-related activities: Examples of direct and significant contribution to the data include but are not limited to:
1. Obtaining Informed Consent
2. Conducting subject recruitment activities
3. Administration of investigational product/Study Drug (when different from routine care)
4. Perform critical trial-related procedures
5. Perform research physical examinations
6. Evaluation of adverse and serious adverse events
7. Determine eligibility

Roles and Responsibilities
The investigator must ensure that his/her staff members directly involved in the performance of research related procedures and/or the collection of data are listed on the Form FDA 1572 as sub-investigators and are adequately trained for their role.

Related Information
1. FDA Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572), May 2010
2. Code of Federal Regulations – 21 CFR 312.60
3. Form FDA 1572, OMB No. 0910-0014
4. FDA Warning Letters: Ref: 08-HFD-45-1001, Ref: 08-HFD-45-1003, Ref: 09-HFD-45-02-01, Ref: 08-HFD-45-09-01, and
## Revision History

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<td>Version 1.0</td>
<td>3/30/2016</td>
<td>Initial Draft Document</td>
<td>Doris Shank</td>
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<tr>
<td>Version 2.0</td>
<td>5/26/2016</td>
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<td>10/28/2019</td>
<td>Revised requirements to align with current regulatory guidance.</td>
<td>Dawn Lundin</td>
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