NIH Intramural Research Program
*Our Research Changes Lives*

**Protocol Clearance by IC Deputy Ethics Counselors (DECs) –**
**A Checklist for Study Teams**

| Questions/Steps | Yes | No |
|---|---|---|
| Is the protocol a Covered Research Protocol (CRP)?<br>***Covered Research Protocol*** *– Covered research protocols (and covered substudies) include: (1) studies of investigational drugs and devices, (2) studies with a research question about a commercially available drug or device, and (3) studies involving collaborations with a substantially affected organization (SAO) or another for-profit entity when the entity is receiving data or specimens from the NIH for the purpose of developing a product. Most interventional protocols will be Covered Research Protocols unless the intervention does not involve the criteria listed above (e.g., a behavioral intervention might not meet the criteria for a covered research protocol or use of a device for physiological exploration where there is no intent to develop a commercial application).* | ☐ | ☐ |
| If **no**, STOP, you do not need to submit to the IC Deputy Ethics Counselor (DEC). If you do have questions about whether your protocol is a covered research protocol, reach out to your IC DEC or IRB@od.nih.gov for guidance. | | |
| If **yes**, and the protocol involves a CRADA or other collaborative agreement with a SAO, or other for profit entity, and when data/specimens will be provided for the purposes of product development, be sure to describe that in the protocol. For example, will the data/specimens that you will share w/your CRADA partner lead to the development of a product? If so make that clear and identify your CRADA partner in the protocol. | ☐ | ☐ |
| If **yes**, provide a copy of the *Guide to Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts of Interest in Clinical Research at the NIH* to all investigators and the study statistician(s) on the NIH study team, including NIH federal employees, non-NIH federal employees, and individuals who are not federal employees. | ☐ | ☐ |
| Submit to the IC DEC for each CRP at each of the following timepoints:<br>1. At the time of Initial Review;<br>2. At the time of each Continuing Review. If removing an investigator(s), be sure to submit a Continuing Review + Amendment form and complete the table showing the removal of any investigators. Submit 6 weeks early for DEC clearance to allow enough time to submit the CR to the IRB, ensuring sufficient time for protocol renewal before the expiration date. (TIP: You can submit CR+AMs to the DEC even if you submit 2 different actions to the IRB later, ask an eIRB system trainer how.)<br>3. Upon request for an Amendment involving the addition of investigators or statisticians; or if removing investigators, complete the table showing who is being removed. That way the DEC does not have to clear investigators who are no longer on the protocol;<br>4. If an on-going protocol becomes a Covered Research Protocol; and<br>5. If there are changes to, or addition of, an IND/IDE, Sponsor or collaborator. | ☐ | ☐ |

| Questions/Steps | Yes | No |
|---|---|---|
| Has the names of *all* NIH study investigators been provided to the DEC?<br>(We recommend submitting the Study Personnel Page (SPP) to provide this information to the DEC. All names listed on the SPP must match the list of names submitted on the DEC Submission Form in the electronic IRB system (eIRB system). Don't forget to remove the names of any investigators who have left the study team) | ○ | ○ |
| Has the name of the NIH study statistician(s) who will evaluate the primary study endpoint been provided to the DEC? This is required even when the statistician **is not designated as a study investigator** on the protocol.<br>(We recommend submitting the SPP with this information to the DEC. Remember to also list the statistician on the DEC Submission form.) | ○ | ○ |
| A. Has each NIH federal employee investigator on the study team been listed on the SPP and on the DEC Clearance Submission in the eIRB system? Such investigators include: NIH federal employees, Special Government Employees (SGEs), or Intergovernmental Personnel Act (IPA) appointees. | ○ | ○ |
| B. Has each non-NIH federal employee investigator and any NIH federal employee statistician(s) on the NIH study team been listed on the SPP and on the DEC Submission form? (Examples of non-NIH federal employee investigators include DoD, FDA, IHS or EPA investigators on detail at the NIH working on an NIH study team.)<br><br>For each non-NIH federal employee investigator or NIH federal employee statistician who is not a financial disclosure filer, collect and submit a current (signed within the past 6 months) *Conflict of Interest (COI) Certification for Non-NIH Federal Employees and NIH Employees Who Do Not File a Financial Disclosure Report* at each relevant time point specified above. | ○ | ○ |
| C. Has each investigator and any statistician(s) who is not a federal employee, who is on the NIH study team, been listed on the SPP and on the DEC Submission form? (Examples of non-federal employee investigators include contractors, IRTAs/CRTAs or other trainees, SV, Guest Researchers working on an NIH study team.)<br><br>For each investigator or statistician who is *not* a federal employee, collect and submit a current (signed within the past 6 months) *Conflict of Interest (COI) Certification for Non Federal Employees* at each relevant time point specified above. | ○ | ○ |
| D. Have all investigators on a CRP complied with the requirements specified in Policy 3014-102 Investigator Conflicts of Interest and Government Royalties? | ○ | ○ |
| E. Have all investigators complied promptly with the PI or study staff requests to review the COI Guide, ensure ethics filings or COI Certification for the protocol are complete and current (within 6 months of a request), as appropriate? | ○ | ○ |

| Questions/Steps | Yes | No |
|---|---|---|
| F. To avoid unnecessary delays in clearance of the protocol, have NIH PIs and NIH federal employee investigators and statisticians responded promptly to any IC Ethics office inquiries and or requirements (such as identifying any competitors to the SAO, or updating or filing the HHS 717-1, if requested)? | ○ | ○ |
| G. Upon receiving clearance of the protocol by the IC Ethics office, has the COI Outcome letter been to the reviewing IRB with the IRB submission? | ○ | ○ |