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)? ***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.*	○	○
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: 1. At the time of Initial Review; 2. At the time of each Continuing Review (CR). If adding or removing an investigator(s) at the time of CR, be sure to submit a Continuing Review+ Modification form, indicating within the Modification form which investigator(s) is being added or removed with the submission. Submit your CR/MOD at least 6 weeks prior to expiration to allow for review and approval by the DEC office and the IRB before the protocol expires. 3. Upon request for an Modification involving the addition of an investigator(s) or a statistician(s); edit the study personnel section of the Modification form indicating which investigator(s) is being added. 4. If an on-going protocol becomes a Covered Research Protocol; and 5. If there are changes to, or addition of, an IND/IDE, Sponsor or CRADA partner.	○	○

Questions/Steps	Yes	No
Have the names of *all* NIH study investigators been included in the submission form? TIP: Don't forget to add names of any new investigators and 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.	○	○
A. Has each NIH federal employee investigator on the study team been listed on the Submission in the eIRB system? The following investigators are NIH ethics filers: 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 Submission form? (The following are non-NIH federal employee investigators, e.g., DoD, FDA, IHS or EPA investigators on detail at the NIH working on an NIH study team.) For each non-NIH federal employee investigator or NIH federal employee statistician who is not an NIH financial disclosure filer, collect and submit a current (signed within the past 6 months) *Conflict of Interest (COI) Certification* 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 Submission form? (Examples of non-federal employee investigators include contractors, IRTAs/CRTAs or other trainees, SV, Guest Researchers working on an NIH study team.) 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* 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. Has clearance of the protocol by the IC Ethics office been indicated in PROTECT as Accepted? (This will notify the IRB that Ethics Clearance is complete)	○	○