**SUBMISSION CHECKLIST FOR**

**SCIENTIFIC REVIEW, PRE-REVIEW, AND INITIAL REVIEW**

**The following items must be completed and uploaded into PTMS for each kind of activity:**

Scientific Review

      PTMS IR Application completely filled out (No sections may be left blank)

      Protocol under the protocol tab. In the document description section, indicate this is the version for the SRC. Include a form of version control within the document (e.g., in a document header or footer). Please do not include Informed Consent Forms within the protocol document. There is a separate tab in PTMS for consent forms, and SRC does not review these documents.

      Planned Enrollment Report Form

      Appendices relevant to the science (as applicable) under the appendices tab

\*\*\*After the SRC review, email to PRIASubmission@mail.nih.gov the Clinical Center Prospective Protocol Resource Assessment Tool (PRIA) Form, and include the Protocol and all Informed Consent Forms. (No protocols will go through without the PRIA form being approved).

Initial Review

The IRB includes a pre-review as part of the review process. Refer to the Scientific Review Committee and Institutional Review Board Calendar <http://www.genome.gov/10005032> for the submission schedule.

      Memo to the IRB Chair. Clean copies of all relevant documents are required to be uploaded. (DO NOT remove previously reviewed documents)

      Memo to the Branch Chief responding to the SRC’s evaluation (put this under the SRC section) Update all relevant documents based on the SRC comments for the IRB to review.

      PTMS IR Application completely filled out (No sections may be left blank)

      Protocol under the protocol tab. In the document description section indicate this is the updated version for the IRB. Include a form of version control within the document (e.g., in a document header or footer). Please do not include Informed Consent Forms within the protocol document. There is a separate tab in PTMS for these.

      Informed Consent Forms – clearly marked and NOT part of the Appendices (there is a separate tab for these in PTMS

      Planned Enrollment Report Form

      Appendices (as applicable) under the appendices tab

      Conflict of Interest (COI – SOP 21): Send the CoI information directly to Ethics (nhgriethics@mail.nih.gov) and copy the IRB office (nhgriirboffice@mail.nih.gov). It does not matter whether the protocol is covered or not because NHGRI Ethics wants to see all protocols at initial review.

      Designation of Reimbursement for Travel and Subsistence (DRTS) – filled out in PTMS (required by Congress for all protocols)

      Radiation Safety Application (if applicable)

      Upload (under the “Other” section) a copy of an email from every AI on the protocol that works at NIH confirming their knowledge of participation on the specific protocol. If they are not a part of NHGRI then also provide an email from their Clinical Director stating that they are approved to participate on the protocol. (OPS will not sign off on any protocol without these approvals)

If your protocol is reviewed by the convened IRB

It usually takes about 5-10 days for the IRB Office to provide the relevant minutes of the convened meeting. The minutes report the decision of the IRB, which will be one of the following Actions:

Approve – Protocol was approved with no stipulations. The IRB Office will send the approved documents directly to the Office of Protocol Services for final sign off.

Approve with Stipulations - Protocol was approved with stipulations. We ask that the investigator respond to the stipulations within 30 days of receipt. Resubmission is done through PTMS. Tracked changes and clean copies of all relevant documents are required to be uploaded. (DO NOT remove previously reviewed documents).

Defer - Protocol was not approved. Substantive stipulations require additional re-submission of relevant documents through PTMS. Tracked changes and clean copies of all relevant documents are required to be uploaded. (DO NOT remove previously reviewed documents).

Table - IRB does not have sufficient information to approve the protocol. Correspondence from the IRB will outline what they believe is necessary for re-review. Tracked changes and clean copies of all relevant documents are required to be uploaded. (DO NOT remove previously reviewed documents).

Disapprove - The study cannot be approved as submitted. Correspondence from the IRB will outline why the project was not approvable. The investigator is allowed the opportunity to respond in person or in writing.