These are some of the criteria that you can ask the PI/study team, the NP/PA if there is one on the team, OCR, etc. to determine if an Authorized User (AU) is needed or not.

First, is the radioisotope itself investigational? Meaning, is it still waiting for FDA approval. Then ask yourself, is an FDA approved isotope being used strictly for investigational purposes? In this instance an Authorized User will be needed.

The following questions are generally more typical of when an Authorized user is going to apply for a Winship Clinic Trial investigating a new cancer medication.

1. Is the Nuclear Medicine exam that is listed in the SoA (i.e., PET/CT scan, bone scan, MUGA, SPECT-CT along with the associated isotope that will be given with it) standard of care for the disease process according to NCCN guidelines used by OCR to draft a cost analysis and budget. If it is considered SOC, an Authorized User is not needed. Is the exam being done strictly for investigational purposes, you will need an Authorized User. You can look at the cost analysis/budget and if you see an M (3rd party payer, Medicare, insurance, etc. it's SOC, if you see an S for sponsor, it is considered research) There are also notes in the columns next to the Nuclear Medicine Exams needed for a trial that gives insight into SOC v. research.
   For example, 68Ga PSMA-11 is FDA approved for men with prostate cancer. In most cases, this would be considered a SOC exam with its associated SOC isotope. Also, 18F-FDG PET-CTs are SOC, etc.
2. In addition to the #1 above, consider the FREQUENCY of the nuclear medicine exam. Once again, if more exams are needed for a clinical trial than are covered by NCCN guidelines and covered by a 3rd part payer, meaning the sponsor will cover the cost of the exam and isotope, then an Authorized User will be needed. Again, look at the cost analysis/budget and see who is paying for what M vs. S.
   For example, MUGA scans are often ordered to assess heart function in patients receiving chemo, so is the MUGA considered SOC and how many will M cover according to NCCN guidelines based on the disease process or is this MUGA scan strictly investigational? Then you know whether to place the MUGA scan in the SOC or Research Column on the Radiation Summary Form and alerts us to complete an Authorized User, etc.

   This is why it's important to wait to see the final budget for a clinical trial, but I know time is of the essence with a lot of these clinical trials, so Radiology can do the best to help you.

   The financial analyst teams that do the budgets and cost analysis for OCR are a great resource for determine if exams and isotopes are SOC vs. research as is Radiology.