ASCO Clinical Trial Workload Assessment Tool

Please list each staff member for whom research-related workload will be entered into the Tool. Please include only research staff who deal directly with patients in ongoing oncology trials in your research program. You will need to enter each staff member's name, the research site that they are affiliated with, their job title, and their FTE applicable to patient-focused research activities.

Staff Member	Site Name	Job Title (Specify Research Nurse, Clinical Research Associate, Research Coordinator, Administrator/Manager) Definitions are provided on the adjacent sheet.	# FTE (Based on working 40 hours per week)

Definitions of roles:

Administrator/Manager: Responsible for research staff and overall research program.
Research Nurse: Licensed registered nurse responsible for: assessing patients for clinical trials; enrolling and monitoring patients (assessing adverse events, etc.); consenting process; communication with physician investigator(s), patient(s) and family/friends; verifying data collected is accurate, etc.
Clinical Research Associate (non-nurse): Unlicensed, with or without college degree, and responsible for: timely and accurate collection, submission and monitoring of clinical trial-associated data; entering patient-specific data into applicable data submission cooperative group and/or industry trial portal(s), etc. May be involved in recruitment and screening process, but has minimal patient contact.
Research Coordinator: Responsible for: protocol evaluation and feasibility, including budget evaluation and trial preparation involving the planning; assembling and instruction of the trial team; development and evaluation of patient information and informedconsent forms; and patient recruitment. May also have responsibilities related to the coordination and management of research staff.
Regulatory Affairs Specialist: Responsible for preparation of required forms and materials for initial and continuing Institutional Review Board (IRB) review, and tracks and completes all regulatory-related processes (reporting of adverse events, amendments, etc. to IRB).

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Please list the ongoing oncology trials in your research program with patients <u>on active treatment</u> only. You will need to provide each trial sponsor name, protocol number, type of trial (i.e., cancer control or treatment), and assign an acuity rating.

Nickname	ClinicalTrials.gov ID Number	Trial Sponsor	Type of Trial (Treatment, Cancer Control, Prevention, Correlative Science/Biospecimen, Observational, Registry, or Other)	Protocol Acuity Score (Score 1 to 4) For instructions, refer to Protocol Acuity Scoring Worksheet on adjacent page.

Trial Sponsor	Protocol Number		Type of Trial (Cancer Control, Treatment, Observational/Registry, Correlative/Biospecimen, or Prevention)	Acuity Rating (Score 1 to 4) For instructions, refer to Protocol Acuity Scoring Worksheet on adjacent page.

Protocol Acuity Scoring Worksheet

STEP 1 **Evaluate the protocol for workload-related elements:**

- ☑ Complexity of treatment,
- ☑ Trial specific laboratory and/or testing requirements,
- ☑ Treatment toxicity potential,
- ☑ Data forms required (consider complexity and number of forms),
- ☑ Degree of coordination required (involvement of ancillary departments, outside offices/sites and/or disciplines),
- ☑ Number of randomizations/steps.

STEP 2 **Assign a score utilizing a range of 1 – 4 as follows:**

Score	Scoring Criteria
1	• Observational/Registry trial • Patients in follow-up status only
2	• Testing oral agents with minimal toxicity • Tests/procedures considered standard of care • Data forms require basic information easily captured from medical record • Requires minimal coordination with outside and/or ancillary staff • Non-randomized or single randomization *(May include standalone laboratory/correlative science studies, cancer control symptom management trials and hormone therapy trials)*
3	• Testing chemotherapy and/or radiation therapy regimen (may include high toxicity potential oral agents) • Increased toxicity potential when compared to a score of "2" • Involves non-standard of care "research" tests/procedures • Data forms more complex and higher in number • Requires coordination with 1 - 2 other disciplines/ancillary departments • Single time point, randomized Phase II or III *(Includes the majority of randomized phase II & III treatment trials)*
4	• Very complex • Multiple drug regimens • High degree of toxicity potential • Involves multiple non-standard of care "research" tests/procedures • Data forms more complex, daily to weekly data collection required and higher in number • Requires coordination with ≥ 2 disciplines/ancillary departments • Multiple randomizations and/or steps *(e.g., bone marrow transplant, leukemia, lymphoblastic lymphoma, myeloma trials)*

Protocols and Acuity Ratings: Trials with Patients on Active Treatment

Trial Sponsor	**Protocol Number**		**Type of Trial** (Cancer Control, Treatment, Observational/Registry, Correlative/Biospecimen, or Prevention)	**Acuity Rating** (Score 1 to 4) For instructions, refer to Protocol Acuity Scoring Worksheet on adjacent page.
Trial Sponsor	**Protocol Number**		**Type of Trial** (Cancer Control, Treatment, Observational/Registry, Correlative/Biospecimen, or Prevention)	**Acuity Rating** (Score 1 to 4) For instructions, refer to Protocol Acuity Scoring Worksheet on adjacent page.

Protocols and Acuity Ratings: Trials with Patients on Active Treatment

Trial Sponsor	Protocol Number		Type of Trial (Cancer Control, Treatment, Observational/Registry, Correlative/Biospecimen, or Prevention)	Follow-up Status (on-study/off active treatment and/or off study/on follow-up)

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Workload Tool Report Template

Report (Month Year)	Site	Research Staff	Staff Title	Sponsor	Nickname	ClinicalTrials.gov ID	Trial Type	Patient Status	Protocol Acuity Score	FTE	#Patient Encounters	Staff Acuity Score	Screening Information