Clinical Trials.gov Registration Work Aid and Checklist; **All fields required by the system have an asterisk. All Required by ICMJE are noted in guidance.**

Elements	Guidance	
Results Point of Contact		**Done**
*Unique Protocol ID	Grant number or HUM, unless dept. has special coding; give a suffix if there may need to be more than one "trial" using this same id, for example in adaptive trial design cases and/or if IRB approval covers more than one phase of a trial.	☐
*Brief Title	Study title (you may need to shorten the title if it is over 120 characters)	☐
Official Title	Full study title ICMJE required	☐
*Email	PI's Email; get primary person working on it too;	☐
*Study Type	Select "Interventional", "Observational" or "Expanded Access." Most studies will be "Interventional." https://register.clinicaltrials.gov/prs/html/definitions.html#StudyType	☐
FDA Regulated Intervention	Select "Yes" if the study contains an FDA regulated intervention. IF you are using a nutrition product, it probably is. **On the device and app side,** this includes NSR devices as well as "exempt" devices. When in doubt, contact UMMS Office of Regulatory Affairs.	☐
*IND/IDE Protocol	Select "Yes" if the study requires an IND. IF in doubt, double check with MICHR MIAP: MICHRMIAP@med.umich.edu. If "Yes" is selected, another section will populate on the homepage of the registration.	☐
IND/IDE Information (This section will only be present if the IND answer is "Yes")		
Section 801 Clinical Trial	Enter "Yes" if the study is an applicable clinical trial. This will almost always be "Yes.";	☐
Delayed Posting	If the study is an unapproved or un-cleared device trial, enter "Yes." However, if you do that, ICMJE requirements will not be met – therefore consider your reason for posting. Contact Regulatory Affairs if necessary. This will most likely be "No."	☐
*IND/IDE Grantor	Select from the dropdown. The answer will most likely be "CDER."	☐
*IND/IDE Number	The IND number is required to submit the registration. (MIAP can submit the IND application without NCT #; and submit amendment once NCT # is obtained .)	☐

	Obtain the IND number as soon as possible from the applicant (the number can be obtained once CDER receives the IND application).	
Secondary ID		
Secondary ID	Enter the HUM # for the study if you haven't already. (i.e. HUM000xxxx) *NOT A REQUIRED FIELD	☐
Issuing Organization	The University of Michigan	☐
Applicable Clinical Trial		
Section 801 Clinical Trial	If the study is a controlled clinical investigation, other than a Phase I investigation, of a drug, biologic, or device (other than small feasibility device trials and pediatric post-market surveillance) subject to US FDA regulations, (even NSR and "exempt" devices, select "Yes."	☐
Delayed Posting	If the study is an unapproved or un-cleared device trial, select "Yes." This will most likely be "No."	☐
Responsible Party		
*Responsible Party	Select "Principal Investigator" from the drop down and enter the Investigator's Name, Official Title, and "University of Michigan " as the Investigator Affiliation.	☐
*Sponsor	For Investigator Initiated trials this should be the PI, and generallywill often be the "University of Michigan Cancer Center."	☐
Collaborators	If it is a multicenter trial, enter the names of the organizations that will be participating. Also include funders.	☐
Review Board		
*Board Approval	Select the IRB approval status from the drop down and enter the date of approval in the "Approval Number" field. Use the HUM # whether it has been approved yet or not.	☐
*Board Name	The University of Michigan Medical School Institutional Review Board	☐
*Board Affiliation	The University of Michigan	☐
*Board Contact	Business Phone: 734-763-4768 Business Email: irbmed@umich.edu Business Address: 2800 Plymouth Road, Building 520, Room 3214, Ann Arbor, MI 48109-2800	☐
Data Safety Monitoring Committee	Check in the IRB application to see if you included one.	☐

Oversight Authorities	United States: Food and Drug Administration or IRB	☐
Summary/Description		
*Brief Summary	Enter a brief summary in lay language and include a statement of the study hypothesis (i.e. The purpose of this study is to determine whether a reduced intensity conditioning regimen for stem cell transplant with donor cells will allow the donor cells to be effective without causing health problems).	☐
Detailed Description	Provide a more extensive description. You can use the study description provided in eResearch, but this does not need to include justifications for why the science is important. You may also want to include whether there are likely to be changes in outcome measures as you go along, especially if it's a pilot study. * NOT REQUIRED	☐
*Measure Type	This will usually be "Number" but may be something else. Choose from the drop down. You may add more than one Category. For example if the Baseline Measure is Prior Surgery, you may add a category: one category title will be "Yes" and one title will be "No."	☐
Study Status		
*Record Verification Date	Month and year you are updating the record	☐
*Overall Recruitment Status	Select from the dropdown.	☐
Why Study Stopped	If the study was terminated prematurely, enter a short explanation. * NOT REQUIRED	☐
Study Start Date	Month and year enrollment begins * NOT REQUIRED	☐
*Primary Completion Date	Enter the month and year for final data collection date for the primary outcome (i.e. if the primary outcome is survival at 1 year, the primary completion date would be 1 year after the last patient accrual). You can obtain a rough estimate by reviewing the protocol and using the estimated end date in eResearch. Select "anticipated" or "actual". This date may need to be revised with subsequent updates. The "actual" date must be recorded in order to enter study results.	☐

Study Completion Date	The date (month and year) that the study was, or is anticipated to be terminated. Select “anticipated” or “actual”. This date may need to be revised.	☐
Study Design		
Primary Purpose	Select from the dropdown. This will only show up if design is interventional Treatment: • Prevention: • Diagnostic: • Supportive Care: • Screening: • Health Services Research: • Basic Science: • Other: describe in Detailed Description. https://register.clinicaltrials.gov/prs/html/definitions.html#IntStudyDesign	☐
*Study Phase	Select from the dropdown. Select “N/A” for studies that do not involve drug or biologic products.	☐
Intervention Model	Select “Single Group”, “Parallel” (participants are assigned to one of two or more groups in parallel), “Cross-over” (participants receive one of two interventions for the initial phase of the study and receive the other intervention during the second phase of the study), or “Factorial” (two or more interventions, each along and in combination, are evaluated in parallel against a control group).	☐
Number of Arms	Number of arms in the study. If a study is a Phase I/II study, and there is only one treatment arm per phase, enter only 1 arm and describe the two phases in the detailed description area.	☐
Masking	Select “Open Label”, “Single Blind, or “Double Blind.”	☐
Allocation	Select “Randomized” or “Non-Randomized.” If the study is a single arm study, select “N/A.”	☐
Study Classification	• Select from the dropdown.N/A: not applicable • Safety: show if the drug is safe under conditions of proposed use • Efficacy: measure of an intervention's influence on a disease or health condition • Safety/Efficacy • Bio-equivalence: scientific basis for comparing generic and brand name drugs • Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the	☐

	body • Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound • Pharmacodynamics: action of drugs in living systems • Pharmacokinetics/dynamics	
Enrollment	Enter the anticipated patient enrollment. Select “Anticipated” from the dropdown. This will have to be revised to “Actual” when the study completes enrollment.	☐
Outcome Measures		
*Title	Click on “Add a Primary Outcome Measure” or “Add a Secondary Outcome Measure” to add an outcome measure. At least one Primary Outcome Measure must be entered. ICMJE requires “key secondaries” as well. These are NOT the aims in eResearch Sec. 1.1.1. They can usually be found in the protocol, sometimes hiding in the statistical analysis part. Enter a single, MEASURABLE, outcome measure (i.e. percentage of patients with progression free survival at 1 year). NOTE, It’s supposed to be that on which statistical power is determined, However, if this is a very small scale or pilot study, you may wish to consider whether this should be expressed in terms of percentage or number of participants with a given response to avoidthe public’s overreliance on small scale outcomes. NOTE too that PRIMARY Outcome Measure will determine the Primary Completion Date as well, so PI should consider how this is chosen, if there will be “follow up measures. Do not use verbs. Outcomes such as “to evaluate” and “to determine” are not MEASURABLE. “Bioequivalence,” “pharmacokinetics,” and “pharmacodynamics” are not specific descriptions of an Outcome Measure because they do not specify by which measures bioequivalence, pharmacokinetics or pharmacodynamics will be assessed. “Safety,” “tolerability,” and “feasibility” are not specific measures. Similarly, “Adverse events” by itself is not sufficient. “Number of participants with adverse events” is specific. *NOTE: EVERY PRIMARY AND SECONDARY OUTCOME YOU ENTER WILL HAVE TO HAVE RESULTS POSTED IF RESULTS ARE REQUIRED	☐
*Time Frame	Specific timeframe at which the outcome measure will be assessed.	☐

	"3 months post treatment" is not specific. Instead enter, up to 3 months or three months. "At follow-up" or "until death" is not specific. Instead enter the estimated time frame "From randomization until death, assessed up to 1 year." "Change" Outcome Measures – Generally two time points (e.g., "baseline and 8 weeks").	
Description	Additional information if needed for clarification * NOT REQUIRED	☐
Safety Issue	Select "Yes" if the outcome measure represents a safety issue (i.e. number of adverse events).	☐
Conditions		
*Conditions or Focus of Study	Enter each study condition, one per line. Use the link at the top of the page, "MeSH," to verify the correct condition term.	☐
Keywords	* NOT REQUIRED; can be pulled from the MeSH table too.	☐
Arms and Interventions		
Study Arms		
*Arm Label	Select "Edit" on the left side of the page to add study arm information. If you need to add a study arm, select "Add an Arm" at the top of the page. The title for the arm should be the study drug specific to that arm (i.e. Docetaxel, or Immunosuppression Taper).	☐
*Arm Type	Select from the dropdown: Experimental – Experimental drug is being administered. Active Comparator – An arm where active drugs are being given but they are not the drugs under study. Used when "control arm" is specified in the protocol and the other arm is experimental. Placebo Comparator – Only placebo is given Sham Comparator – Only a mock therapy (not a drug) is given. No Intervention Other Intervention	☐

Arm Description	Describe the intervention being given. For drugs include the dosage and frequency. Use the same drug names in the description that are listed as the interventions.	☐
Study Interventions		
*Intervention Type	Select “Edit” on the left side of the page to add study intervention information. If you need to add a study intervention, select “Add an Intervention” at the top of the page. Select the intervention type from the dropdown list.	☐
*Intervention Name	Enter the name of the study intervention Make sure the name entered is the same name entered under the Arm Description. It helps if these harmonize with the Arm Description names, but if there are multiple interventions per arm it may not be possible.	☐
Other Names	Enter additional intervention names such as brand names if applicable.	☐
Intervention Description	Enter any information that was not included in the Arm Description.	☐
Arm/Intervention Cross Reference		
*Cross Reference	This section is only required if there is more than one study arm. Select “Edit” on the left side of the page and check the appropriate interventions that may be administered to each arm.	☐
Eligibility		
*Eligibility Criteria	Copy and paste the Inclusion/Exclusion criteria from the protocol or enter the criteria by hand. If pasted from the protocol review the information for correct format and punctuation, especially regarding age limits	☐
*Gender	Select eligible patient gender (Male, Female or Both)	☐
*Age Limits	Enter the minimum and maximum age at enrollment and select the unit of measure (i.e. years) from the dropdown. If there is no minimum/maximum, select “N/A” from the drop down	☐
Accepts Healthy Volunteers	“Yes” or “No”	☐
Central Contact		
*Central Contact	Enter the Name and Phone Number, and Degree for the Principal Investigator or assistant as preferred by the PI Note: Degree and first	☐

	name are not required.	
Include a Central Contact Backup	Include if desired * NOT REQUIRED	☐
Study Officials		
Study Official	Select “Add” to add a study official. Enter the Principal Investigator’s Name, Degree, Role and Organizational Affiliation (University of Michigan). ICMJE required.	☐
Locations (Enter all Locations if Multisite)		
*Facility	Select the link “Add a location” at the top of the page. Enter The University of Michigan for the facility name.	☐
*Recruitment Status	Select from the Dropdown:	☐
*Facility Contact	Enter the name of Principal Investigato r or assistant as preferred Name, Phone Number, and Email. (Degree is optional)	☐
Facility Contact Backup	Include if necessary * NOT REQUIRED	☐
Citations		
Citations	OPTIONAL Click on “Add” at the top of the page. Enter the MEDLINE Identifier (this is the study PMID) which can be found by locating the publication on PubMed (the PMID will be listed below the study abstract). Select “Yes” if the publication is reporting study results.	☐
Links		
Links	OPTIONAL This is for links like https://umclinicalstudies.org/ if it’s being used. lick on “Add” at the top of the page. Enter the URL and link description and select “Save.”	☐