Grant Writing Bootcamp

Principles of Preaward Research Administration

Health Colleges Research Services (HCRS)

College of Human Medicine – Dean's office

February 26, 2026

HCRS

Health Colleges Research Services (HCRS) provides pre- and post-award support to units in the Colleges of Human Medicine, Osteopathic Medicine, College of Nursing, and various Henry Ford Health departments.

The HCRS team:

- **Cathy Grysiewicz, Preaward Manager, Preaward Manager**
- **Teresa Thomas, Postaward Manager**
- Lu Liu, Research Administrator, preaward / postaward
- Dana Gunderson, Research Administrator, preaward / postaward
- Jourden Ashi, Research Administrator, preaward / postaward
- Inna McNamara, Research Administrator, preaward
- Ryan Johnston, Research Administrator, preaward
- Morgan Forbush, Research Administrator, preaward
- Kristen Bilyea, Research Administrator, preaward
- Melissa Wilson, Research Administrator, postaward
- Lisa Reichstetter, Research Administrator, postaward
- Julie Robinson, Research Administrator, postaward

The HCRS team

Agenda

Topic 1: Deadline policies & Proposal Development

Topic 2: Budgeting

Topic 3: Just In Time (JIT)

MICHIGAN STATE UNIVERSITY

SPARTANS WILL.

Principles of Pre-Award Research Administration

Topic 1: Deadlines & Proposal Development

Cathy Grysiewicz & Lu Liu
Health Colleges Research Services (HCRS)

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Ask us for help, it is our job to help

HCRS.Proposals@msu.edu

We don’t know what you don’t know

Resources

- Additional resources on the SPA website
  - Sponsor Information (link)
  - Frequently Required Information (link)
- Deadline policy (link)
- HCRS intake form (link)
- HCRS email: HCRS.Proposals@msu.edu
- NIH budgeting (link)

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Why are deadlines important?

What does an “at-risk” proposal mean?

Dreaded Deadlines

- We request this timeframe so that we are adequately prepared for the hundreds of proposal requests that are submitted to our unit.
- Our mission is to serve our Investigators in the preaward process to the best of our ability and to submit proposals with utmost accuracy.
- To meet MSU's 10;5;3 deadline policy, we must have advance notice of your proposals.
- Why does it take so long?
  - OSP's policy is a 2-day turnaround for any request
  - Routing in KR could take up to 2 days to complete
  - Completion of COI and/or research security training

Please be mindful of our deadline policy as it is to serve you as well as all of the other Investigators that we serve.

MSU Proposal Deadline Policy Basics

10 days

- Provide OSP with solicitation (RFP, RFA, BAA, etc.)
- Include PD number in notification

6 days

- Send final budget for review and approval
- Route PD once ready

3 days

- Final application package due to OSP

1 day

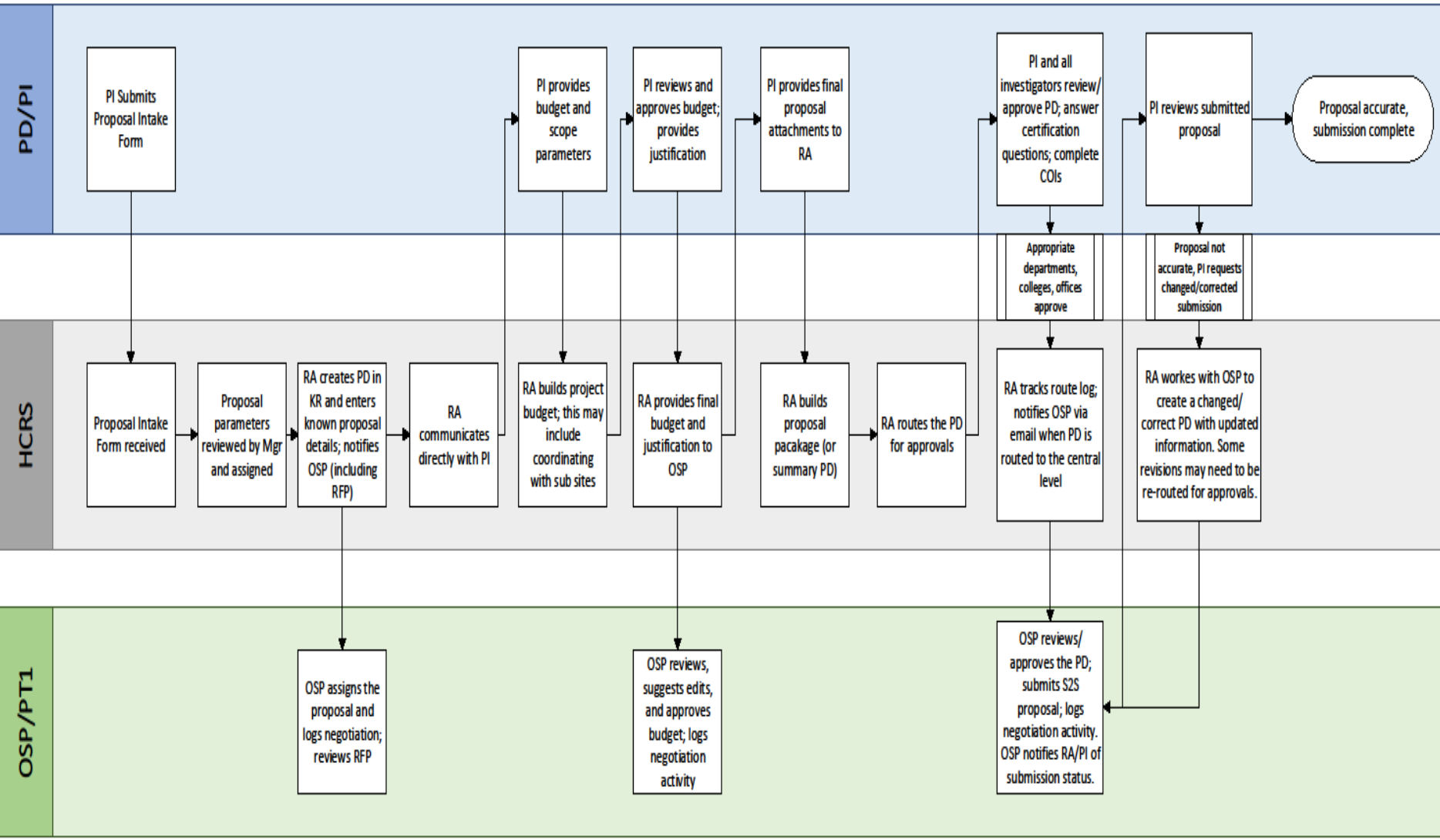
- Proposal is considered “at risk” and must be approved by the Associate Dean for Research and potential disciplinary actions discussed before review & submission by OSP

When do I start a Proposal?

- As soon as you *think* of submitting a proposal, complete an intake form through HCRS.
- HCRS policy, 8 weeks notice prior to Sponsor's deadline date.
- HCRS will not be able to accept short turnaround proposals.
  - If you submit a LOI, submit an intake form so we are aware of your possible full submission.

Don't be this guy!

Michigan State University Health Colleges Research Services Preaward Workflow



HCRS Responsibilities

- Create a checklist for PI based on the solicitation with instructions on how to complete the documents.
- Each agency has different guidelines checklist will be specific to your solicitation, but it is important that the PI reads the solicitation carefully to ensure they include specific information within the application.
- If the proposal includes subawards, the RA coordinates collection of those documents. Initiate communication with sub sites early, provide a sub checklist, and check in often.
- RA reviews documents for compliance with sponsor solicitation and formatting requirements.
- It is the responsibility of the PI to read the solicitation and understand the requirements
  - Always verify if a LOI is required (30 days prior to deadline)

HCRS Responsibilities

- PI provides budget parameters; we build the budget and work with the PI to finalize.
- Create a Proposal Development (PD) document in Kuali Research (KR) and upload all required documents.
- Ensure the PI is familiar with their responsibilities (completion the COI, approvals in KR, timelines).
- Provide templates for required documents and general guidance.

Finding Funding

- Office of Research and Innovation (OR&I) (link)
- MSU Libraries (link)

Electronic Proposal Systems

- Kuali Research
  - System to System (S2S) transmission of proposals to federal government
- Some federal NON-S2S transmissions still exist
  - EERE Exchange - DOE
  - Research.gov - NSF
  - ASSIST – DHHS/NIH
- Foundations/Associations – some have electronic systems
  - Blue Cross Blue Shield Foundation
  - American Heart Association
- State of Michigan
  - EGrAMS for MDHHS
- Proposal Central (100+ agencies)
  - https://proposalcentral.com/

READ funding opportunity for submission details

Types of Proposals

- Proposal submitted by OSP as “Authorized Organizational Representative”
- PI or unit submitted, requires Authorized Official signature
- PI or unit submitted, does not require signature of an Authorized Official

Proposal Review – OSP Submits

*3 full business days prior to deadline to be considered on-time **includes PD***

What are some of the things OSP reviews?

Compliance requirements (FCOI)

Comparison of application to PD

Administrative review comparing to RFP (Recommended vs. required changes)

PI has primary responsibility to know and meet requirements

If a proposal does NOT require submission by OSP nor the signature of an Authorized Official, should you still work with HCRS or your preaward administrator on the proposal?

Proposal Review – PI or Unit Submits

AO signature required

- Fully routed PD (i.e., to OSP) required before signature provided
- Provide OSP with a copy of the final proposal as submitted

AO signature not required

- Fully routed PD still required prior to submission
- Provide OSP with a copy of the final proposal as submitted

Who has signature authority at MSU?

After-the-Fact Proposals/Awards

A proposal was submitted, but the pre-award process was never completed.

What are potential consequences?

PI(s) will not get credit for the submission	Research Dean will be notified	Proposal processing will receive lower priority	Agreement review and negotiation held until proposal process complete	We may not be able to accept the award

Student awards

For proposals submitted System-to-System (e.g., NIH F31 Ruth L. Kirschstein Predoctoral Individual National Research Service Award),where the sponsor requires the fellow to be listed as the PI the fellow/student must be listed as the PI in the Kuali Research (KR) system. The mentoring faculty member should also be included as a Key Person (Mentor).

For all other fellowship or student award applications (e.g., Blue Cross Blue Shield of Michigan Foundation Student Award, The Arnold P. Gold Foundation Student Award), the mentoring faculty member should be listed as the PI in the KR system, as they are ultimately responsible for the award. The fellow/student should be included as a Key Person (Fellow or Mentee).

If you have any questions, please reach out to the HCRS Proposal team or your unit administrator. Awards provided directly to a student rather than MSU will need to be treated as income by the student.

Michigan State University
&
Henry Ford Health + Michigan State University Health Sciences

- Currently, all NIH proposals submitted by MSU faculty in the Health Collages will require the applicant organization listed as HFH+MSU HS, regardless if your proposals includes Henry Ford collaborators.
- All NON-NIH will require a subaward agreement with Henry Ford collaborators until further notice.

Key Personnel

- **Key Personnel**
  - HCRS will need to know all key personnel as soon as possible, both MSU and non-MSU
  - NIH defines **key personnel** as: "People who contribute to a project's scientific development or execution in a meaningful way. This can include the program director (PD) or principal investigator (PI), consultants, and others."
  - **Other Significant Contributor**: "commit to contribute to the scientific development or execution of the project but are not committing any specified measurable effort (person months or percent effort) to the project."
  - Key persons will include a biosketch and an eRA Commons ID, non-key do not require a biosketch nor an eRA Commons ID
- **Credit Allocation:**
  - Confirm F&A allocation with the PI – often weighted average of effort
  - Only the PI and Co-Investigators will default in the combined credit split panel.
  - **COI Disclosure:**
  - All MSU key persons must approve the PD and complete a project-based COI at the time of routing. Annual COI must be up-to-date.
  - Key personnel not associated with an institution (i.e. Consultants) must provide a paper COI.

Key Personnel – ORCID & eRA Commons Accounts

- **Key Personnel – this includes any subaward key persons and/or consultants and collaborators:**
  - All key persons MUST have their ORCID and eRA Commons ID's linked
  - Key persons who do not have a linked account cannot be listed as key persons
  - NIH has a validation warning / error that will not allow the proposal to be submitted if accounts are not properly linked
  - Your ORCID ID may appear at the top of your biosketch but that does not indicate the accounts have been properly linked
  - Only the Investigator (the owner of the SciENcv profile and eRA Commons account) can perform the ORCID ID linking in SciENcv and eRA Commons; delegates cannot complete the linking on their behalf.
  - For all new hires or transferring faculty, be sure to update your eRA Commons profile with your new MSU email address and request an updated affiliation with MSU

Other Proposal Considerations

- **Limited Submission** (link) refers to limitations on the number of proposals a university/institution/college may submit. A proposal that is by invitation only after an LOI is not considered a limited submission.

- A sponsor that limits or prohibits indirect costs is **not** considered an **F&A rate less than allowed by sponsor**. If a proposal uses a lower rate than what is outlined in the solicitation ore MSU's negotiated rate agreement, an F&A waiver is required.

- For **International Activities**:
  - For NIH S2S proposals, include Foreign Justification as Other Attachment

Compliance

- Indicate if vertebrate animals will be used in your project
- Human subjects vs. human data or specimen
- Answers to these questions will determine the required documents for your proposal.

Human Subject Research

- It is very important that you **accurately** determine if human subject research is being proposed.
- Different documents are required for research with human data, and/or specimens that does not meet the criteria for human research.
- If you are new to human subjects research, NIH provides helpful a tool in making your determination.
- Additional flow charts and details in appendix

Human Subjects Research

Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

Examples of human subjects research include:

- Collecting blood
- Conducting a survey
- Changing participants' environment
- Administering medicine
- Interviewing
- Administering a psychological test
- Collecting data
- Conducting a focus group
- Testing a new educational technique

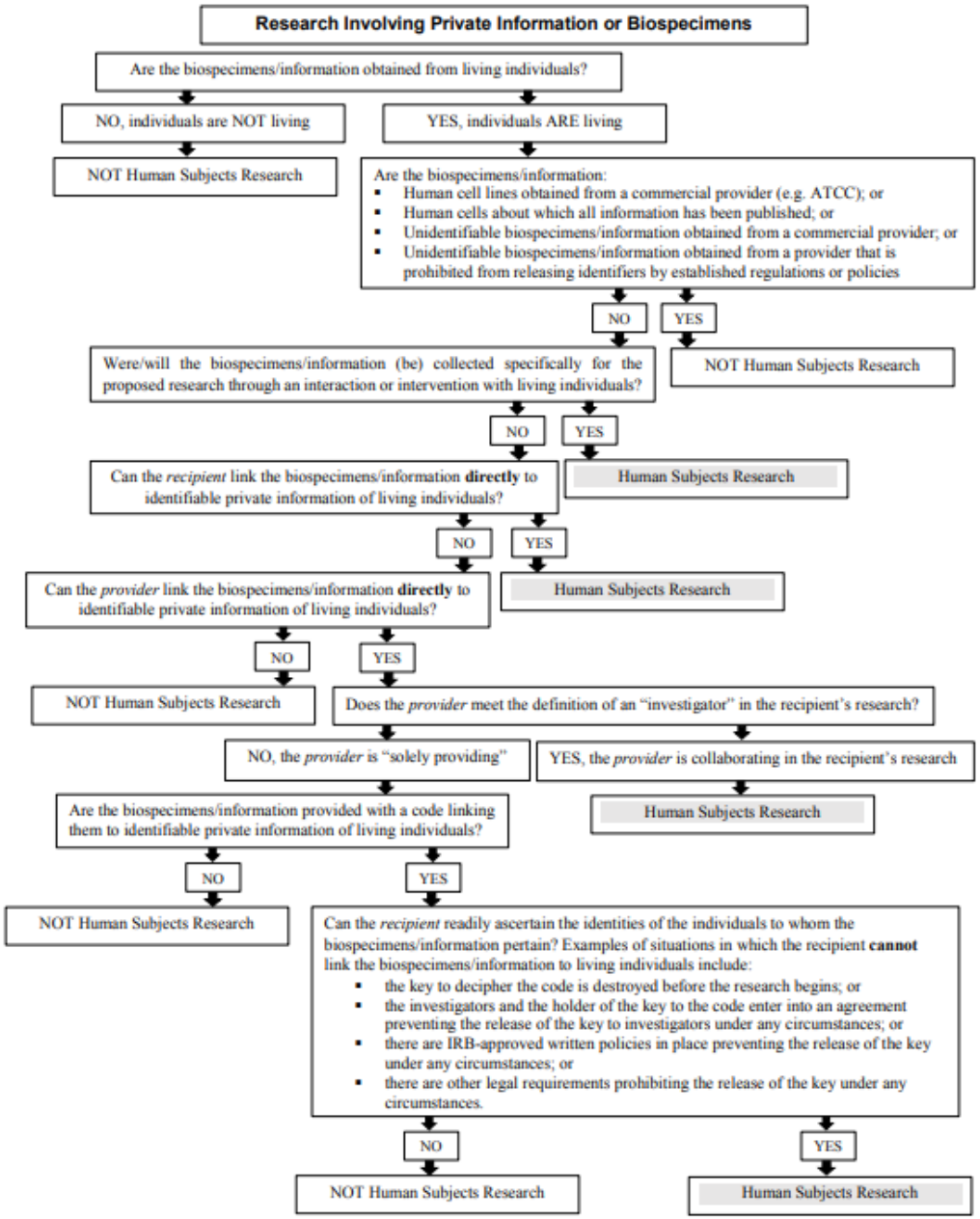
Included in the NIH application:

✓ Protection of Human Subjects attachment

If funded, grantees will need:

✓ An Institutional Federal-Wide Assurance (FWA) with OHRP

✓ IRB approval or determination of exemption



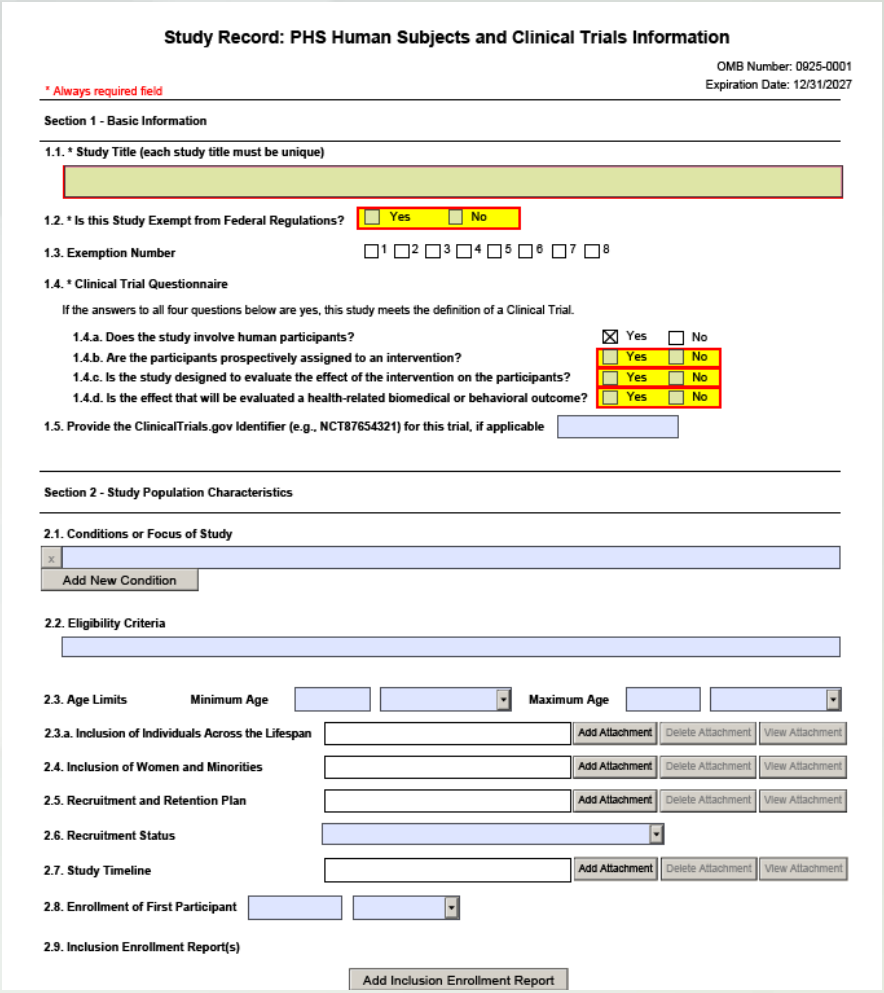
Please note: this document is intended to be a resource only. Final decisions should be made in accordance with 45 CFR 46.

NIH Office of Extramural Research - June 25, 2019

Infographic: Research Involving Private Information of Biospecimens

Human Subjects Research, YES. Now, what?

- You know your research involves human subjects. The next questions are:
  - Is your project exempt? If so, what is the exemption #?
  - Is your study delayed onset?
  - Is the study a clinical trial?
  - You will need to complete the PHS Human Subjects Study Record once you have the above answers. Each determination has different document requirements.
- OSP created a human subjects information guide that can be provided from your research admin. This guide provides robust details and information on how to successfully complete this form.



Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 12/31/2027

* Always required field

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☐ No

1.3. Exemption Number ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

1.4. * Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants? ☒ Yes ☐ No
1.4.b. Are the participants prospectively assigned to an intervention? ☐ Yes ☐ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? ☐ Yes ☐ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ☐ Yes ☐ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Add New Condition

2.2. Eligibility Criteria

2.3. Age Limits Minimum Age Maximum Age

2.3.a. Inclusion of Individuals Across the Lifespan — Add Attachment | Delete Attachment | View Attachment
2.4. Inclusion of Women and Minorities — Add Attachment | Delete Attachment | View Attachment
2.5. Recruitment and Retention Plan — Add Attachment | Delete Attachment | View Attachment
2.6. Recruitment Status
2.7. Study Timeline — Add Attachment | Delete Attachment | View Attachment
2.8. Enrollment of First Participant
2.9. Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

Human Subjects Research

- Once the Table has been determined (exempt, clinical trial or non-exempt), follow the guidelines and documents required.
- If your study is a delayed onset, enter your study title, complete questions in 1.4 and attach your justification.
- Some projects will have multiple study records.

Is your research a Clinical Trial or Clinical Study?

- NIH defines a clinical trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions(which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

- The following questions will determine if your research is a study or trial:
  1. Does the study involve human participants?
  2. Are the participants prospectively assigned to an intervention?
  3. Is the study designed to evaluate the effect of the intervention on the participants?
  4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

** If all answers are yes, your study is a clinical trial.

Submission of Proposal

- HCRS will route your PD into submission
  - Prior to submission, they will validate your application to clear and warnings or errors.
  - They will provide you with a copy of the full application for your review.
  - HCRS will provide guidance for approving the PD in KR and completing the COI module. They will monitor the route log and submit to OSP for final review.
  - Upon submission to OSP for final review, which can take up to 2 days, you will be notified that your proposal has been submitted, if S2S. If non-S2S, you will be notified that you may submit your proposal to the Sponsor.

Questions?

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BUDGETING FOR PROPOSALS

Types of Budgets

- Detailed budget – NIH
  - Full detailed budget will be submitted with application
- Modular Budget – NIH
- NIH uses a modular budget format to request up to a total of $250,000 of direct costs per year (in modules of $25,000, excluding consortium F&A costs) for some applications, rather than requiring a full detailed budget.

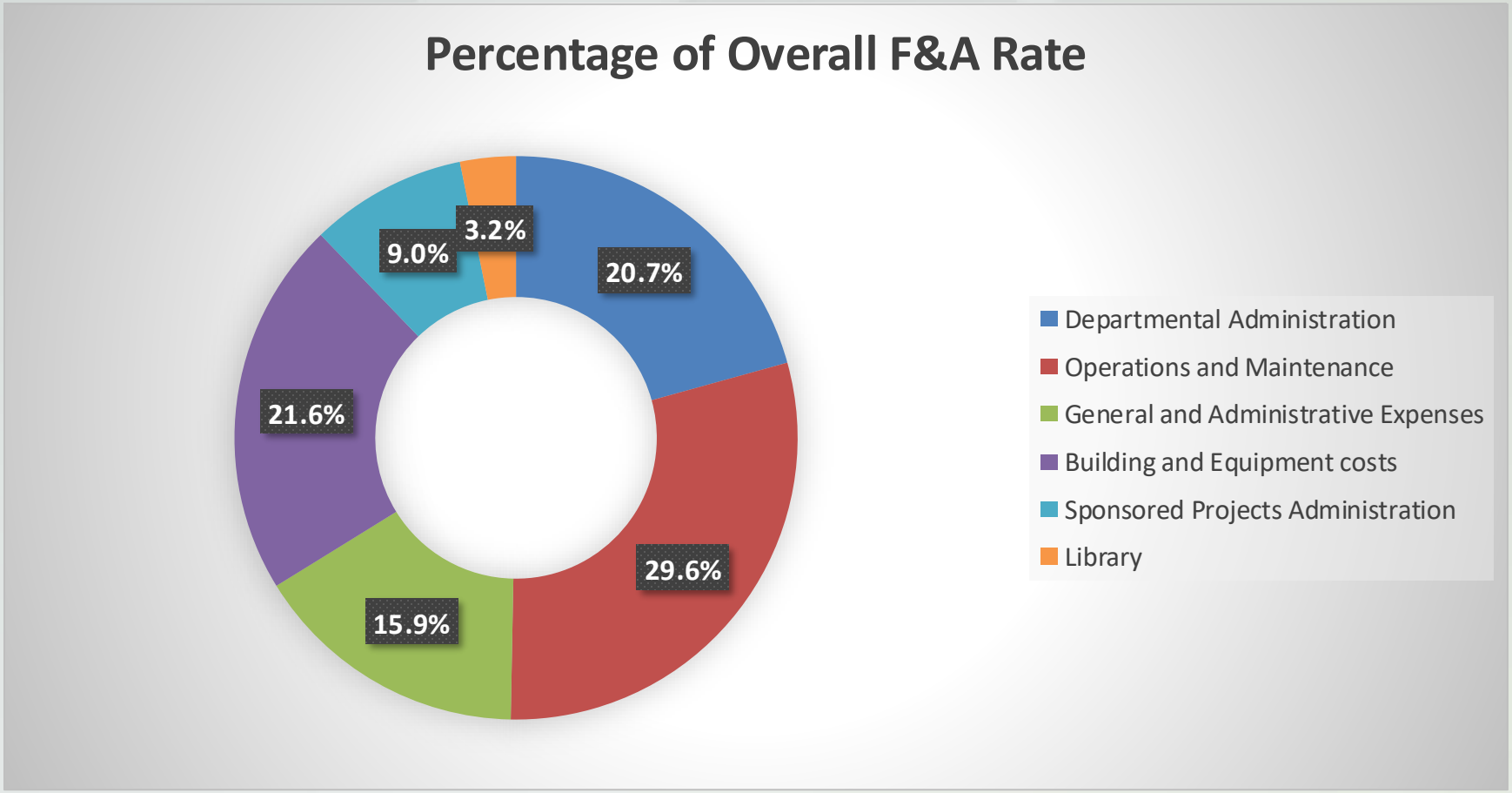
The modular budget format is NOT accepted for;

- SBIR and STTR grant applications,
- applications from foreign (non-U.S.) institutions (must use detailed budget even when modular option is available), or
- applications that propose the use of human fetal tissue (HFT) obtained from elective abortions (as defined in NOT-OD-19-128 for HFT) whether or not costs are incurred.

Direct Costs vs. Indirect Costs

- What is the difference between allowable direct costs and allowable facilities & administrative (F&A) costs?
- **Direct Costs:** Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
- **F&A Costs:** Necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of F&A (indirect) costs. F&A (indirect) cost pools must be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived.

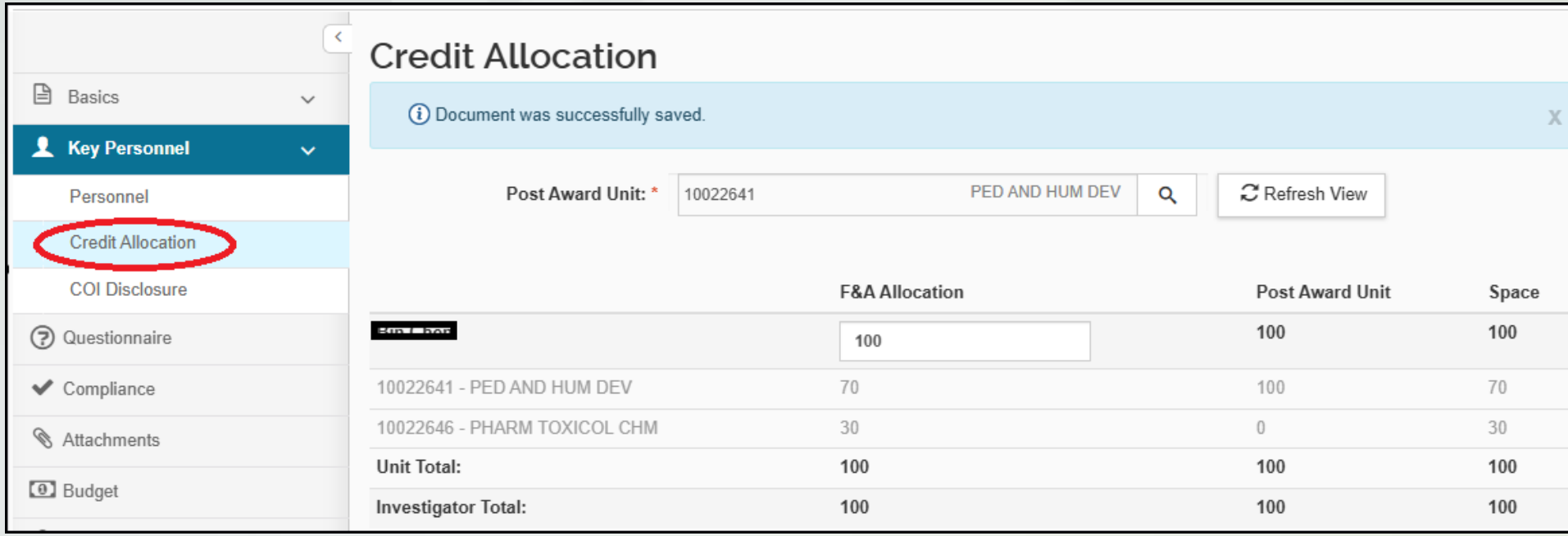
Indirect Cost Return



Link to OSP for more information (link)

PI Profile

- Be aware that your PI profile is set up correctly so when you go up for promotion and tenure your proposals are credited to you.
- Credit allocation: Bigger portion of overhead return.



Cost Share

- Cost sharing
- Avoid voluntary cost share
- Must have prior approval documenting the resources of the cost share
- In-kind effort federal funds not recommended due to high audit risks
  - Consider Other Significant Contributor (OSC)
  - An email from your Chair approving in-kind effort is acceptable

HCRS role in creating a budget

- Provide budget parameters to HCRS and we will create a budget in excel that shows your target maximum allowable costs and the difference based on your budget parameters
- KR will pull salaries and fringe rates directly from EBS.
- Fringe rates are based on specific identification, which means they fluctuate depending and increase over time. Thus, even removing inflation will mean slight increases in your budget personnel costs across years

Inflation

- Inflation: MSU defaults to roughly a 3% inflation increase is salaries. It is the PI's discretion to include inflation or turn off inflation in out years
  - Inflation is always, by industry standard, applied to year 1 (base rate) to all budgets.
  - NIH does not have a policy on inflation, however several IC's specify they will not award inflation. This means that NIH will cut the award AND cut inflation.

Budgeting

- HCRS will provide general guidance on budgeting expenses, however it is the PI's responsibility to know the actual costs of their project and obtain quotes when applicable
- HCRS will provide guidance and examples of a budget justification, but it expected that the PI will write the budget justification.
- HCRS will modify the budget justification as changes to the budget are made throughout the budget process.

Just In Time (JIT)

- These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding.
- Direct email from GMS; forward to your dept admin and they will help facilitate the JIT documents and inform OSP JIT for correspondence with NIH
- Typical documents requested:
  - Updated Current/Pending/Other Support of all key person
  - IRB or IACUC / compliance approval documentation
  - Human subject education certification
  - May also include:
    - Requested changes to the DMS plan
    - Requested changes to the budget

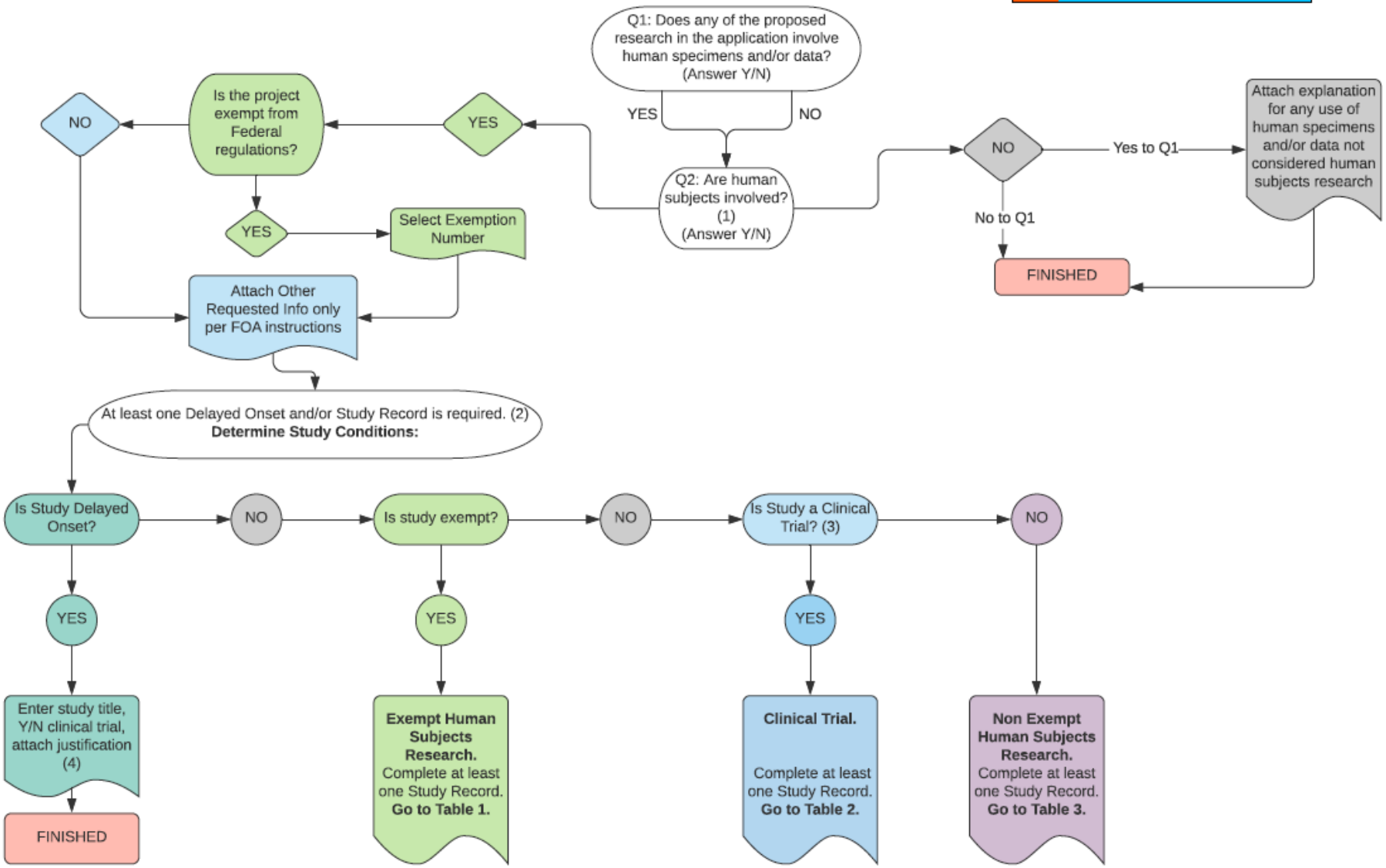
Questions?

Appendix

Additional Human Subjects Information

PHS Human Subjects and Clinical Trials Information Forms-G

Link:updated webpage in SPA



(1) Response to "Are Human Subjects Involved?" must match the response on the R&R Other Project Information.
(2) A proposal may include both Delayed Onsets and Study Records. Complete the appropriate sections for each portion of the project.
(3) See NIH definition of a clinical trial: https://grants.nih.gov/policy/clinical-trials/definition.htm
(4) Multiple delayed onset studies may be combined in a single delayed onset record.
These guidelines are generally applicable to R-series proposals. Please refer to the FOA for specific instructions. See also the NIH Application Guide Section G.500 for details on this form.

NIH Exempt Human Subjects Research

8 Exemptions

Consider

1 Meets the definition of human subjects research.

Exempt studies involve human subjects research: research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

2 Meets the criteria of one of the following exemptions:

Exemption 1: conducted in an educational setting using normal educational practices*

*Cannot include any other procedures, such as collection of clinical data or biospecimens

Exemption 2: uses educational tests, surveys, interviews, or observations of public behavior*

*Limited IRB review may be required.

Exemption 3: benign behavioral interventions in adults*

*Limited IRB review may be required.

Exemption 4: involves the collection/study of data or specimens if publicly available, or recorded such that subjects cannot be identified*

*May be identifiable in limited cases. See §46.104(d)(4)(iii) and (iv)

Exemption 5: research or demonstration projects designed to study, evaluate, improve, or examine an *NIH* public benefit or service program*

*Applies to projects that NIH itself administers

Exemption 6: taste and food quality evaluations

Exemption 7: storage of identifiable information or biospecimens for secondary research use. *Broad consent* and *limited IRB review* are required

Exemption 8: secondary research use of identifiable information or biospecimens. *Broad consent* and *limited IRB review* are required

NIH Requirements:

- HS education
- Inclusion tracking for all except 4.

45 CFR 46 Requirements:

- Limited IRB review for 7 & 8, and some study designs under 2 & 3.
- Broad consent for 7 & 8.

Cannot involve **prisoners**, unless includes a broader population that happens to include prisoners.

Cannot involve **children** in:

- Exemption 2 if investigators participate in the activity being observed or includes identifiable info, OR
- Exemption 3.

For more information see the NIH OER Human Subjects Research website.
Send questions/comments to OER-HS@nih.gov.

Exemption 1 (X1)

✓
- Effectiveness of on-line training as supplement to regular instructional approach.
- Effectiveness of activities to increase awareness of oral health delivered at a community science museum

⊘
- Testing a manual for parents to identify severe asthma symptoms
- Evaluation of health education that includes collection and analysis of heart rate and body measurements from students

Exemption 2 (X2)

✓
- Focus group of adult community members to discuss access to dental care
- Questionnaire about outdoor exercise, including collection of participants' age and zip code (limited IRB review conducted)

⊘
- Substance abuse training for individuals engaged in illegal drug use, followed by a survey about the training
- Investigator-led focus group of pre-teens to discuss bullying

Exemption 3 (X3)

✓
- Study among young adults evaluating preferred snack foods following a television program
- Study investigating text vs. voice message appointment reminders on self-reported annual physical appointment attendance

⊘
- Diet and physical activity intervention for people with diabetes
- Examining reactions of participants during brief exposure to painful stimuli

Exemption 4 (X4)

✓
- Patient data extracted from medical records without name or ID number every 6 months as follow up visits occur
- A collaborator removes an aliquot of blood from coded samples. Aliquots are re-labeled to a random, non-linked code

⊘
- De-identified blood drawn from subjects for the study by a blood bank
- Use of collaborator's coded tissue samples and the collaborator retains the code key

Exemption 5 (X5)

✓
- Outcomes evaluation of NIH conducted mental health service program*

*NOTE: NIH anticipates use of this exemption will be rare

⊘
- Evaluation of U.S. state administered service program
- Evaluation of investigator-sponsored diabetes intervention

Exemption 6 (X6)

✓
- Evaluation of wholesome food preferences
- Study looking at approved levels of an agricultural chemical on taste of vegetables

⊘
- Study evaluating novel food additives
- Testing high doses of environmental contaminant on food taste

Exemption 7 (X7)

✓
- Creating a dataset containing identifiers from a previous study to conduct future research*
- saving blood samples from collaborator's study for a future research question*

*(Broad consent obtained and limited IRB review conducted.)

⊘
- Dataset containing identifiers from prior study stored for future research, with informed consent for study-specific research (no broad consent)

Exemption 8 (X8)

✓
- Using dataset from prior study containing identifiers to answer subsequent research question*
- Using blood samples from collaborator's study for an additional research question*

*(Broad consent obtained and limited IRB review conducted.)

⊘
- Using blood drawn from subjects with study specific consent for future research question

✓ = exempt ⊘ = non-exempt

Please note: these are possible examples of exempt research accepted by NIH. Final determination of exemptions should be made in accordance with 45 CFR 46.

Exempt Human Subjects Research

Study Record
Table 1

Exempt Human Subjects Research

Section 1 - Basic Information	Required	
1.1 Study Title	Required	
1.2 Exempt?	YES	
1.3 Exemption Number	Required	→ Should match selection on PHS Human Subjects and Clinical Trials Information form
1.4 Clinical Trial Questionnaire	At least one question NO	→ 1.4.a "Does the sudy involve human participants?" defaults to Yes and is not editable
1.5 ClinicalTrials.gov Identifier		

	Exemption Number (1.3 above)		
	E4[1] ONLY	All other Exemptions[2]	
		YES	
Section 2 - Study Population Characteristics	**Not Required**	**Required**	
2.1 Conditions or Focus of Study		Required	→ Up to 20 conditions, limited to 255 characters each
2.2 Eligibility Criteria		Required	→ Use dash+space for bulleted list
2.3 Age Limits		Required	
2.3.a. Inclusion of Individuals Across the Lifespan		Required	
2.4 Inclusion of Women and Minorities		Required	
2.5 Recruitmen and Retention Plan		Required	
2.6 Recruiment Status		Required	
2.7 Study Timeline		Optional	
2.8 Enrollment of First Participant		Required	
2.9 Inclusion Enrollment Report(s)	**Not Required**	**Required**	→ Up to 20 reports can be added per study record
1. Inclusion Enrollment Report Title		Required	
2. Existing Dataset or Resource?		Required	
3. Enrollment Location Type		Required	
4. Enrollment Country(ies)		Optional	→ Autopopulates to USA for domestic; multi-select from list
5. Enrollment Location(s)		Optional	→Type of location, not name
6. Comments		Optional	
Planned Table		Required if NOT using an existing dataset or resource	
Cumulative (Actual) Table		Required if using an existing dataset or resource	
Section 3 - Protection and Monitoring Plans	**Required**	**Required**	
3.1 Protection of Human Subjects	Required	Required	
3.2 Multi-site study?	Required	Required	→ Choose "N/A" for exempt
Single IRB plan attachment			
3.3 Data and Safety Monitoring Plan	Optional	Optional	
3.4 Data and Safety Monitoring Board?	Optional	Optional	
3.5 Overall Structure of Team	Optional	Optional	

Table 1

Section 4 - Protocol Synopsis	**Do not complete**	**Do not complete**
Section 5 - Other Clinical Trial-related Attachments	**Do not complete**	**Do not complete**
	↓ Finished. Attach to PHS Human Subjects and Clinical Trials Information form.	↓ Finished. Attach to PHS Human Subjects and Clinical Trials Information form.

[1]Exemption 4 ONLY
[2]Any exemption other than E4 only, or any combination of exemptions including E4.

Guidelines are generally applicable to NIH R-series proposals; please refer to the FOA for specific instructions.
Refer to the NIH Application Guide Section G.500 (link above) for details and content requirements:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

Step 1: Determine exemption number
Step 2: If exempt 4, follow left column. All other exemptions, follow left column.

Non-Exempt Human Subjects Research

Section 1 - Basic Information	Required	
1.1 Study Title	Required	
1.2 Exempt?	NO	
1.3 Exemption Number		
1.4 Clinical Trial Questionnaire	At least one question NO	→ 1.4.a "Does the sudy involve human participants?" defaults to Yes and is not editable
1.5 ClinicalTrials.gov Identifier		
Section 2 - Study Population Characteristics	**Required**	
2.1 Conditions or Focus of Study	Required	→ Up to 20 conditions, limited to 255 characters each
2.2 Eligibility Criteria	Required	→ Use dash+space for bulleted list
2.3 Age Limits	Required	
2.3.a. Inclusion of Individuals Across the Lifespan	Required	
2.4 Inclusion of Women and Minorities	Required	
2.5 Recruitmen and Retention Plan	Required	
2.6 Recruiment Status	Required	
2.7 Study Timeline	Optional	
2.8 Enrollment of First Participant	Required	
2.9 Inclusion Enrollment Report(s)	**Required**	→ Up to 20 reports can be added per study record
1. Inclusion Enrollment Report Title	Required	
2. Existing Dataset or Resource?	Required	
3. Enrollment Location Type	Required	
4. Enrollment Country(ies)	Optional	→ Autopopulates to USA for domestic; multi-select from list
5. Enrollment Location(s)	Optional	→Type of location, not name
6. Comments	Optional	
Planned Table	Required if **NOT** using an existing dataset or resource	
Cumulative (Actual) Table	Required if using an existing dataset or resource	
Section 3 - Protection and Monitoring Plans	**Required**	
3.1 Protection of Human Subjects	Required	
3.2 Multi-site study?	Required	→ If YES, contact IRB office to develop sIRB Plan (irb@ora.msu.edu)
Single IRB plan attachment	Not Required if NIH	→ If AHRQ and 3.2 is YES, attach IRB Plan (for NIH, plan will be required at JIT stage)
3.3 Data and Safety Monitoring Plan	Optional	
3.4 Data and Safety Monitoring Board?	Optional	
3.5 Overall Structure of Team	Optional	
Section 4 - Protocol Synopsis	**Do not complete**	
Section 5 - Other Clinical Trial-related Attachments	**Do not complete**	

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Clinical Trial

Table 2

Clinical Trial

Section 1 - Basic Information	Required	
1.1 Study Title	Required	
1.2 Exempt?	NO	
1.3 Exemption Number		
1.4 Clinical Trial Questionnaire	All questions YES	→ 1.4.a "Does the sudy involve human participants?" defaults to Yes and is not editable
1.5 ClinicalTrials.gov Identifier	Optional	
Section 2 - Study Population Characteristics	**Required**	
2.1 Conditions or Focus of Study	Required	→ Up to 20 conditions, limited to 255 characters each
2.2 Eligibility Criteria	Required	→ Use dash+space for bulleted list
2.3 Age Limits	Required	
2.3.a. Inclusion of Individuals Across the Lifespan	Required	
2.4 Inclusion of Women and Minorities	Required	
2.5 Recruitmen and Retention Plan	Required	
2.6 Recruiment Status	Required	
2.7 Study Timeline	Required	
2.8 Enrollment of First Participant	Required	
2.9 Inclusion Enrollment Report(s)	**Required**	→ Up to 20 reports can be added per study record
1. Inclusion Enrollment Report Title	Required	
2. Existing Dataset or Resource?	Required	
3. Enrollment Location Type	Required	
4. Enrollment Country(ies)	Optional	→ Autopopulates to USA for domestic; multi-select from list
5. Enrollment Location(s)	Optional	→Type of location, not name
6. Comments	Optional	
Planned Table	Required if NOT using an existing dataset or resource	
Cumulative (Actual) Table	Required if using an existing dataset or resource	
Section 3 - Protection and Monitoring Plans	**Required**	
3.1 Protection of Human Subjects	Required	
3.2 Multi-site study?	Required	→ If YES, contact IRB office to develop sIRB Plan (irb@ora.msu.edu)
Single IRB plan attachment	Not Required if NIH	→ If AHRQ and 3.2 is YES, attach IRB Plan (for NIH, plan will be required at JIT stage)

Clinical Trial

Study Record
Table 2

Section 4 - Protocol Synopsis	Required	
4.1.a Detail Description	Required	→ Up to 32,000 characters
4.1.b Primary Purpose	Required	
4.1.c Interventions	Required	→ Up to 20 interventions allowed
4.1.d Study Phase	Required	→ Select Y/N NIH Phase III
4.1.e Intervention Model	Required	
4.1.f Masking	Required	→ aka Blinding; if Yes, select type(s)
4.1.g Allocation	Required	
4.2 Outcome Measures	Required	→ At least 1, up to 50 allowed
4.3 Statistical Design and Power	Required	
4.4 Subject Participation Duration	Required	
4.5 FDA-regulated intervention?	Required	→ If yes, 4.5.a explanation required
4.6 Applicable clinical trial under FDAAA?	Required	
4.7 Dissemination Plan	Required	→ Same can be used for multiple studies; filename must be unique f
Section 5 - Other Clinical Trial-related Attachments	**Only include per FOA**	

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Finished.
Attach to PHS Human Subjects and Clinical Trials Information form.

Guidelines are generally applicable to NIH R-series proposals; please refer to the FOA for specific instructions.
Refer to the NIH Application Guide Section G.500 (link above) for details and content requirements:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm