Please note: On February 20, 2017, a newly revised protocol submission form was implemented in the eprotocol system. All currently active Expedited and Full Board studies must be converted to the new form through a new protocol submission. This guide provides detailed instructions for completing the protocol form transition.

Detailed Protocol Transition Guide

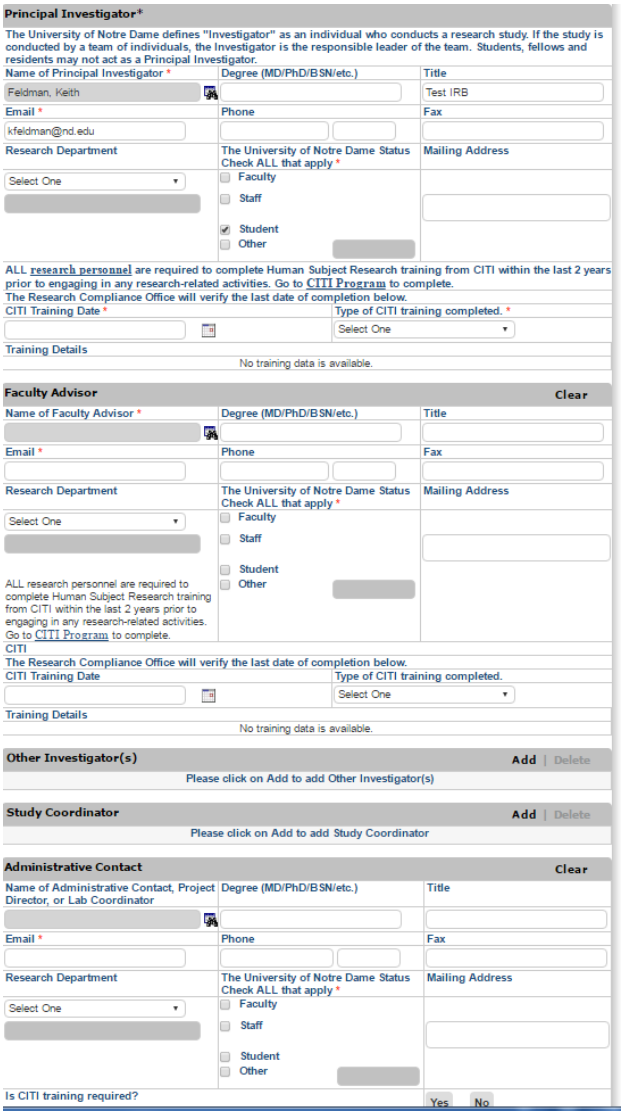
This guide is intended as a resource to assist study teams in converting their already-approved IRB studies to the new protocol submission form in eprotocol. Used along with the Protocol Transition Quick Guide, a researcher will be able to complete the process without interruption of their research. The guide provides information highlighting new questions in the revised protocol submission form, but emphasizes where information from the previously approved protocol can be used within the new submission form.

Notre Dame Research Compliance encourages all researchers to review their already-approved IRB studies to determine if they need to transition, and plan to complete the transition process by submitting the protocol on the new submission form leaving adequate time for review before study expiration. For Full Board studies, this means submitting at least two weeks before the last IRB meeting before study expiration. For Expedited studies, this means submitting no later than three weeks before study expiration, but our office strongly encourages study teams to submit as early as they possibly can to allow time for review comments and responses.

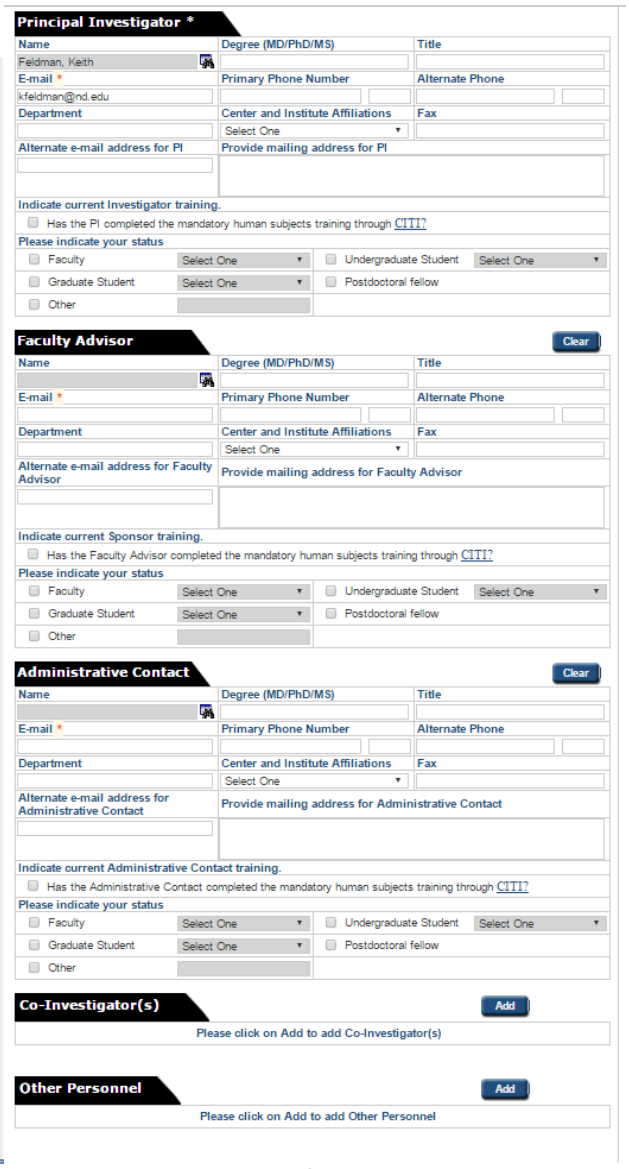
If you have any questions about the Protocol Transition, please don't hesitate to contact our office at compliance@nd.edu.

Personal Information:

- CITI Training Details are now pulled directly in for an individual based on their NetID
  - If training details fail to load the certifications can be manually entered
    - Training is no longer a mandatory field, but the protocol may be sent back to determine relevant training if human subjects are involved
- A new field has been added for a Study Coordinator



New Form 1



Previous Form 1

Previous Form: "Subject Checklist"

New Form: "Vulnerable Subject Checklist"

- The Subject checklist remains mostly unchanged
    - Some items have been moved to new locations within the form
        - *Community Research* is now found on the **Study Location Tab**
        - *Internet* has been moved to the **General Checklist**
        - *Individuals residing in a foreign country* and *International population* can be identified on **Protocol Information – 5. Subject Population (k)**, by answering "Yes"
        - *Patients* are selected by choosing *Medical/Healthcare Facility* in **Study Location**
    - Some subject group descriptions have changed
        - *No Vulnerable populations* has been replaced with *Healthy Adult volunteers*
        - *Decisionally Impaired* is now *Persons incompetent to give consent*
- Question (b), which asked for justification for enrolling vulnerable subject populations, has been moved to **Protocol Information – 5. Subject Population (c)**

Subject Checklist

	Select All That Apply :
☐	Economically/educationally disadvantaged
☐	Elderly
☐	Healthy Adult volunteers
☐	Homeless
☐	Illiterate
☐	Institutionalized patients/residents
☐	Mentally Ill
☐	Military personnel
☐	Minors (under 18)
☐	Non-English Speakers
☐	Persons incompetent to give consent (e.g., dementia, comatose, have legal guardians)
☐	Pregnant women (Upload "Research Including Pregnant Women" Form)
☐	Prisoners (Upload "Research for Including Prisoners" form)
☐	Public officials/candidates for public office
☐	Students (Elementary or secondary) (Upload a letter of agreement/permission from the schools.)
☐	University employees
☐	University students
☐	Other (please specify):

New Form 2

Vulnerable Subject Checklist*

a)	Select all that apply.
☐	College students (i.e., University of Notre Dame, St. Mary's College)
☐	Community research (i.e., local organizations)
☐	Decisional Impaired (**Please complete and attach the Request to Include Participants with Impaired Decision Making Capacity form that can be found in the resource library of our website: research.nd.edu)
☐	Economically Depressed Populations
☐	Elderly ("Elderly" does not necessarily mean "vulnerable." Explain below what makes the population vulnerable, e.g., senile dementia.)
☐	Individuals within organizations (i.e., NGOs, military)
☐	Individuals residing in a foreign country
☐	International population (**Please complete and attach the International/Transnational Research form that can be found in the resource library of our website: research.nd.edu)
☐	Internet based research (**Please complete and attach the Internet Research form that can be found in the resource library of our website: research.nd.edu)
☐	Minors (under 18 years of age) (**Please complete and attach the Research Involving Children as Participants form that can be found in the resource library of our website: research.nd.edu)
☐	Neonates
☐	Non-English Speakers
☐	Patients (i.e., Epworth Center, Oaklawn, Memorial Hospital)
☐	Pregnant Women (**Please complete and attach the Research Involving Pregnant Women form that can be found in the resource library of our website: research.nd.edu)
☐	Prisoners (**Please complete and attach the Research Involving Prisoners form that can be found in the resource library of our website: research.nd.edu)
☐	Students - Secondary + Elementary (need signed Letter of Agreement from school(s))
☐	No vulnerable populations will be included.
☐	Other (i.e., any population that is not specified above)

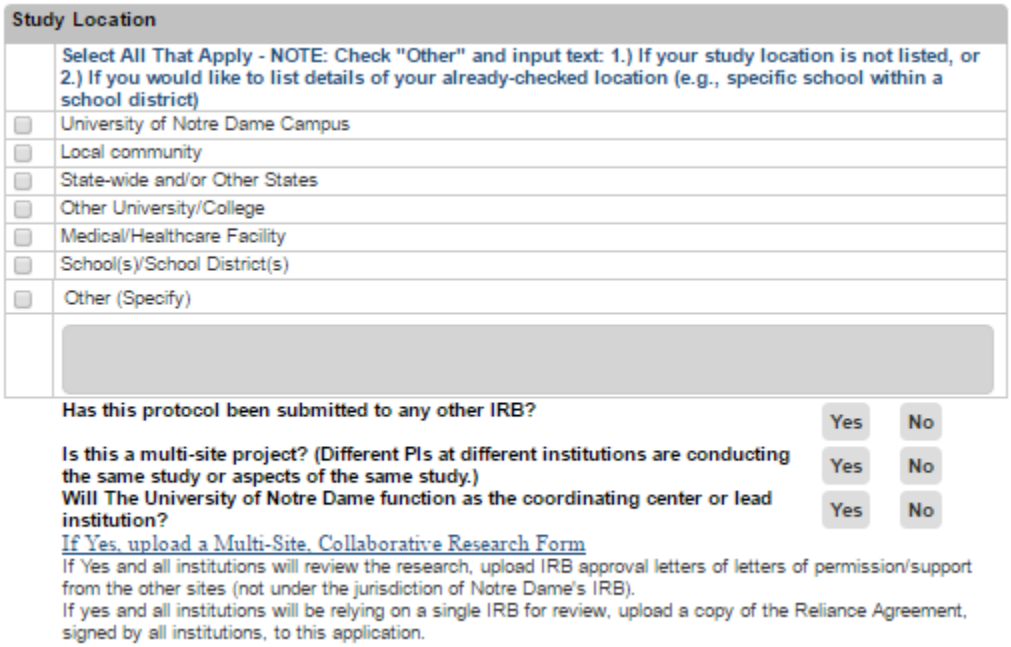
b) **If any proposed subjects are children/minors, prisoners, pregnant women, those with physical or decisional impairments, or others who are considered vulnerable to coercion or undue influence, state your rationale for their involvement.**

c) **If your research targets non-English speakers, explain your knowledge of local community attitudes, cultural norms, and cultural sensitivities necessary to carry out the study.**

Previous Form: N/A

New Form: Study Location

- This form indicates where the research will be taking place
  - *State-wide and/or Other States* indicates research taking place at a scale larger than a community outside of a university setting
- The Multi-Site Study questions below the Study Location field are new
  - These questions are used to identify studies which require reliance agreements or collaboration between researchers at different institutions
  - *Has this protocol been submitted to any other IRB?*
    - Has this protocol been submitted (or is planned to be submitted) to another IRB by researchers collaborating on the **same study** (the same data collection and population being evaluated)
  - *Is this a multi-site project?*
    - Different PIs at different institutions are conducting the same study, either all study procedures or a component of a larger protocol
  - *Will The University of Notre Dame function as the coordinating center or lead institution?*
    - The PI for a study with Notre Dame as lead institution will be required to provide a detailed plan for coordination between sites, including communication between sites.



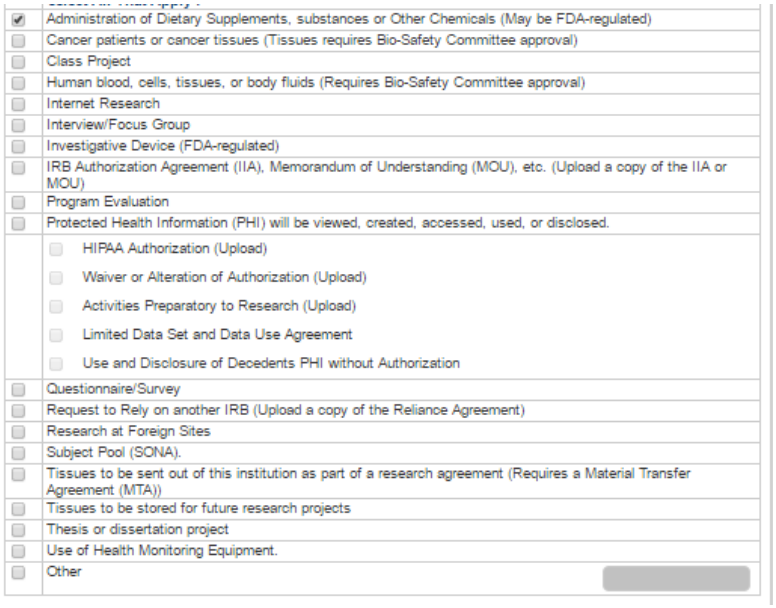
New Form 3

Previous Form: General Checklist

New Form: General Checklist

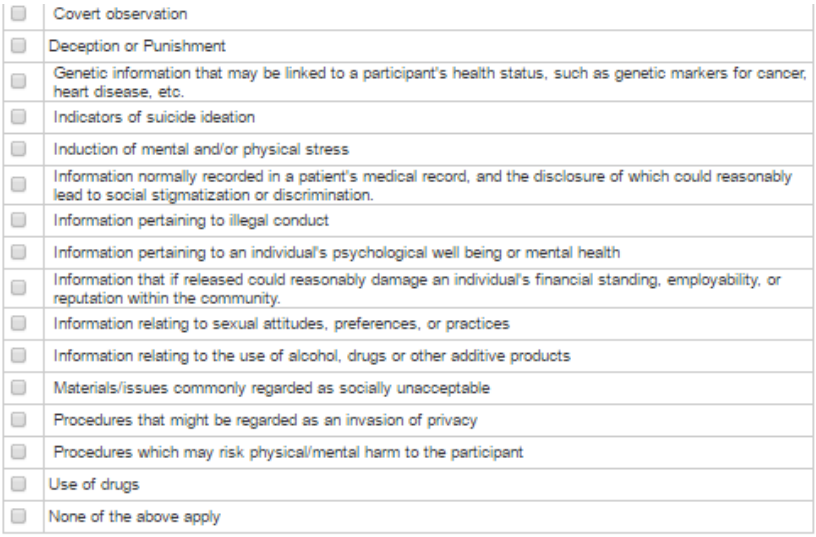
This form has changed significantly

- Now: The form focuses on the types of data, and how the data will be collected.
  - These questions now influence which questions are required in **Protocol Information**
- Was: A majority of items (such as *Deception, Procedures that might be regarded as an invasion of privacy, Induction of mental stress*) have been moved to **Protocol Information**



☑	Administration of Dietary Supplements, substances or Other Chemicals (May be FDA-regulated)
☐	Cancer patients or cancer tissues (Tissues requires Bio-Safety Committee approval)
☐	Class Project
☐	Human blood, cells, tissues, or body fluids (Requires Bio-Safety Committee approval)
☐	Internet Research
☐	Interview/Focus Group
☐	Investigative Device (FDA-regulated)
☐	IRB Authorization Agreement (IIA), Memorandum of Understanding (MOU), etc. (Upload a copy of the IIA or MOU)
☐	Program Evaluation
☐	Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.
	☐ HIPAA Authorization (Upload) ☐ Waiver or Alteration of Authorization (Upload) ☐ Activities Preparatory to Research (Upload) ☐ Limited Data Set and Data Use Agreement ☐ Use and Disclosure of Decedents PHI without Authorization
☐	Questionnaire/Survey
☐	Request to Rely on another IRB (Upload a copy of the Reliance Agreement)
☐	Research at Foreign Sites
☐	Subject Pool (SONA).
☐	Tissues to be sent out of this institution as part of a research agreement (Requires a Material Transfer Agreement (MTA))
☐	Tissues to be stored for future research projects
☐	Thesis or dissertation project
☐	Use of Health Monitoring Equipment.
☐	Other

New Form 4



☐	Covert observation
☐	Deception or Punishment
☐	Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
☐	Indicators of suicide ideation
☐	Induction of mental and/or physical stress
☐	Information normally recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
☐	Information pertaining to illegal conduct
☐	Information pertaining to an individual's psychological well being or mental health
☐	Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.
☐	Information relating to sexual attitudes, preferences, or practices
☐	Information relating to the use of alcohol, drugs or other additive products
☐	Materials/issues commonly regarded as socially unacceptable
☐	Procedures that might be regarded as an invasion of privacy
☐	Procedures which may risk physical/mental harm to the participant
☐	Use of drugs
☐	None of the above apply

Old Form 4

Previous Form: Funding

New Form: Funding

This page remains almost unchanged

- The major change is now funding is broken down by where it issued
    - Funding must be added one award at a time rather than as free-text

New Form 5

Old Form 5

Protocol Information

- Protocol Information was previously initiated by the review type (Exempt, Expedited, Full) selected when the protocol was created, from which a category could be picked.
- In the new form the protocol type is selected at the start of the protocol information from the following checkbox:

Application type checklist	
☐	Not Human Subjects Research
☐	Exempt
☐	Expedited/Full Board

Please note Expedited and Full Board are now selected as one item

- The protocol category or categories are selected under the same review categories as within the previous form

PLEASE READ: For Expedited Review, all aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve one or more of the specific categories listed below.

Select the following applicable categories to determine if your research project qualifies under Expedited Review. If none of the categories are applicable to your research project, a Full Committee Review will be required. For Expedited or Full Review, proceed to complete the following application.If none of the expedited criteria are appropriate for your project, please move to the next screen WITHOUT checking any of these criteria; your protocol will be reviewed by the full IRB. Note: The IRB will make the final determination if your protocol is eligible for expedited review.

Select one or more of the following paragraph(s):

☐ **1. Clinical studies of drugs and medical devices only when condition (a) and (b) are met.**

a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b) Research on medical devices for which

i) An investigational device exemption application (21 CFR Part 812) is not required; or
ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**

a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

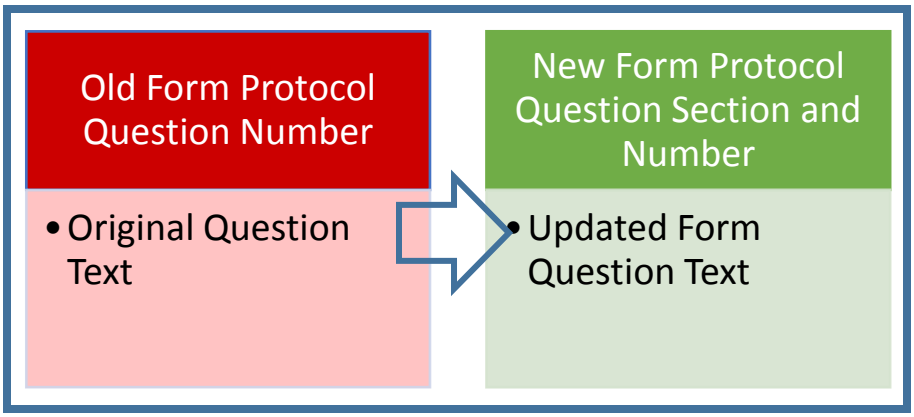
b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ **3. Prospective collection of biological specimens for research purposes by non-invasive means.**

Examples:
a) Hair and nail clippings in a non-disfiguring manner;

The format of the protocol information has changed. The following sections are formatted as below:

Old Form Protocol Information Tab location 1-4 5 6 7 8 9 10 11 12 13 14



Protocol **1-4:** 1(a)	Protocol **Summary:** 2(a)
• State the problem and hypothesis	• Describe the purpose for the proposed project as well as the hypotheses / research questions to be examined

Protocol **1-4:** 1(b)	Protocol **Background:** 4(a)
• Provide the scientific or scholarly reason for this study and background on the topic	• Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.

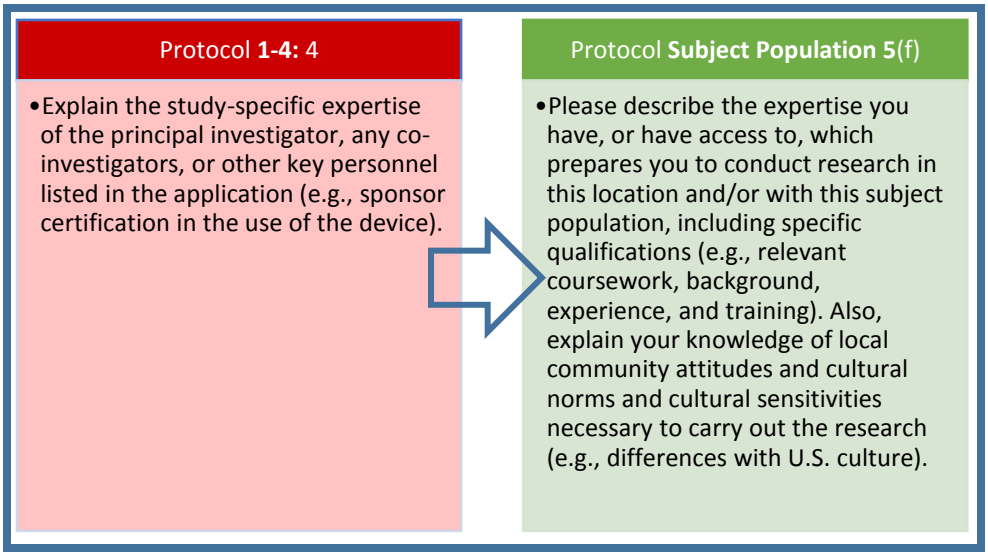
Protocol **1-4:** 2(a)	Protocol **Summary:** 2(b)
• List the purpose(s) of the study (what are you hoping to learn as a result of the study)	• Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined. • What do the investigators hope to learn from this project?

Protocol **1-4:** 3(a)	Protocol **Summary:** 3(a)
• Describe data collection methods (Procedures) be specific	• Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures.

If your study includes standard care or treatment procedures, you will need to identify them and distinguish them from experimental procedures. In addition, if you are altering standard care or treatment you will need to identify treatment or care that subjects could choose instead of participating in your study. If neither of apply to your study, please enter "N/A"

- Summary 3(a)(i)
  - Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures.
- Background 4(c)
  - Alternative Procedures. Describe any alternatives to participating in the research. (e.g., standard of care treatment, etc.). Any standard treatment that is being withheld must be disclosed. This information must be included in the consent form.

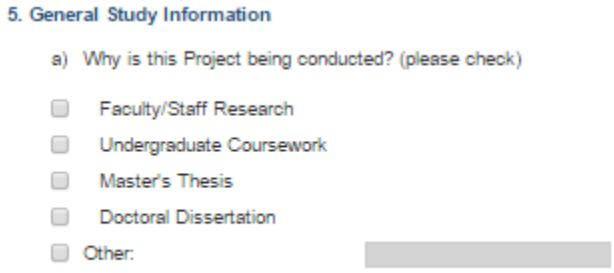
Protocol **1-4:** 3(b)	Protocol **Background:** 4(b)
• Describe the specific materials or tools that will be used to collect the data - be specific	• Describe the statistical methods of the research and plans for analysis of the data (i.e. planned statistics, justification of sample size, etc.).



New Fields:

- **Protocol Information**: **Summary**
  - 1a is a new field representing a brief (elevator pitch) review of the project
  - 3c-f
- **Protocol Information: Background**
  - **4d/e**

Protocol 5: 



These options are now included in the **General Checklist**

Protocol **6:** (a)	Protocol **Subject Population 5**(b)

• Inclusion and Exclusion Criteria (what participant traits are needed to be included, what traits exclude participants?)	• Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.)
	  • Identify inclusion criteria.
	  • Identify exclusion criteria.

Protocol **6:** (b)	Protocol **Subject Population 5**(c)
• What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?	• What is the rationale for studying the requested group(s) of participants?

Protocol **6:** (d)	Protocol **Recruitment Process: 6 (a-c)**
• Recruitment procedure (if applicable) including who will recruit participants	• See Image below

Protocol **Recruitment Process: 6 (a-c)**

a) **Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.**
- **List any specific agencies or institutions that will provide access to prospective subjects.**
- **Identify who will contact prospective subjects and how**

b) **Planned Subject Identification Methods:**

- ☐ N/A
- ☐ Chart/database review
- ☐ Class participants
- ☐ Circumstance (e.g., homelessness)
- ☐ Organization mailing lists
- ☐ Other (please specify):
- ☐ Direct advertising
- ☐ Living conditions (e.g., nursing home residents)
- ☐ From PI's own practice/clinic
- ☐ Referrals
- ☐ The University of Notre Dame Subject Pool

c) **Planned Recruitment Materials/Methods:**

- ☐ N/A
- ☐ Phone Scripts
- ☐ Television ads
- ☐ Letters to prospective subjects
- ☐ Oral Scripts
- ☐ Internet ads/postings
- ☐ Face to face interactions
- ☐ Other (please specify):
- ☐ Flyers/posters
- ☐ Letters to providers/schools/organizations
- ☐ Newspaper ads
- ☐ Radio ads
- ☐ PowerPoint presentations
- ☐ Email
- ☐ The University of Notre Dame Subject Pool

Protocol **6:** (e)

- Recruitment procedure (if applicable) including who will recruit participants

Protocol **Recruitment Process: 7 (a-g)**

- See Image below

Protocol **Recruitment Process: 7(a-g)**

7. Subject Compensation and Costs:

a) Will subjects receive compensation for participation? Yes No

Total amount (in dollars or equivalent)

b) Form of Compensation:

- ☐ Cash
- ☐ Check
- ☐ Gift card/certificate
- ☐ Voucher
- ☐ Raffles/lotteries
- ☐ Course/extra credit
- ☐ Reimbursement only
- ☐ Other (please specify)

c) Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether a 1099 will be issued.)

d) For raffles include the number of prizes, nature and value of each prize.

e) If extra course credit is offered be sure to address the alternative means by which students can accrue extra course credit should they not wish to participate in the study.

f) Will subjects or their health care providers be required to pay for any study related procedures or products? Yes No

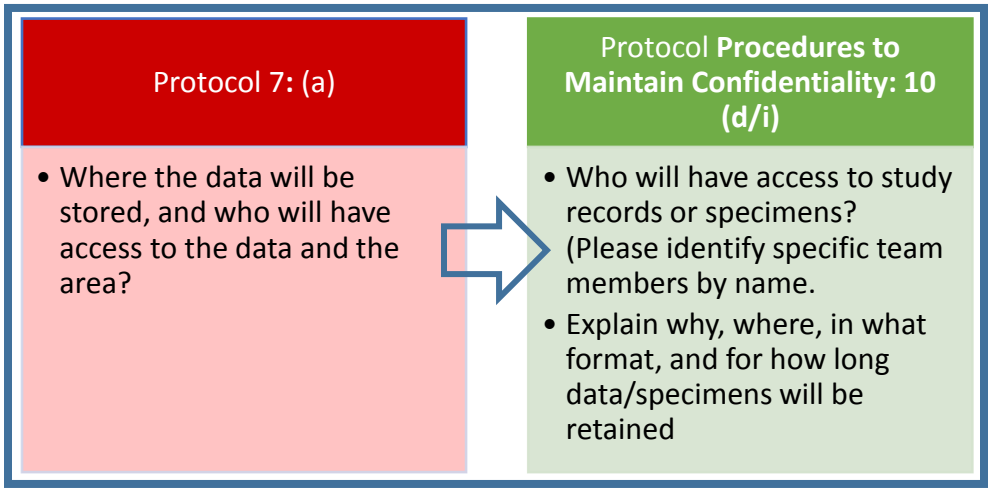
i. If yes, explain:

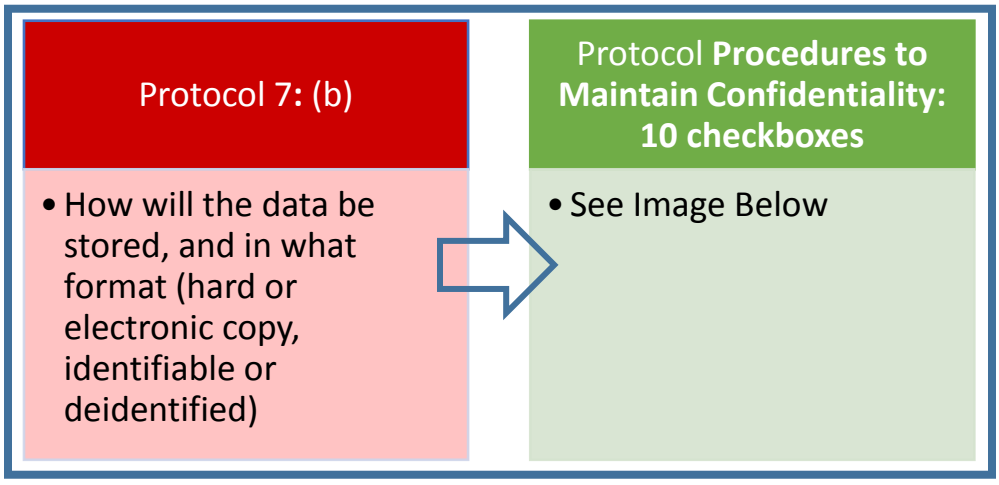
Additional Information

- Protocol Information 6c on the old form is no longer directly referenced

New Fields

- **Protocol Information**: **Subject Population**
  - 5a - *How many subjects to you intend to enroll and/or how many subject records to you intend to access?*
    - PI's must now specify an estimate of the number of subjects they wish to recruit
    - a-ii is only valid for multi-site studies as denoted in **General Checklist**





Protocol **Procedures to Maintain Confidentiality:**

10. Procedures to Maintain Confidentiality

Which of the following types of data will you work with:

☐ Identifiable
Information is considered to be identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person or investigator could ascertain the identities of individuals. Therefore, even though a dataset may have been stripped of direct identifiers (names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g., age, gender, ethnicity, and place of employment).

☐ Anonymous
Data are anonymous if no one, not even the researcher, can connect the data to the person who provided it--no identifying information is collected from the individual. Investigators must be aware, however, that even if no direct identifiers (name, address, student ID, etc.) are collected, identification of a participant may be possible from unique individual characteristics (indirect identifiers). For example, a participant who is a member of a certain ethnic group or who was studied because of distinctive personal accomplishments or medical history might be identifiable from even a large data pool.

☐ De-identified
If the dataset has been stripped of all identifying information and there is no way that it could be linked back to the subjects from whom it was originally collected (through a key to a coding system or by any other means). Note: This also applies if the source of the data is identifiable but the data collected is not.

☐ Coded
This refers to data that have been stripped of all direct subject identifiers, but in this case each record has its own study ID or code, which is linked to identifiable information such as name or medical record number. The linking file must be separate from the coded data set. This linking file may be held by someone on the study team (e.g. the PI) or it could be held by someone outside of the study team (e.g. researcher at another institution). A coded data set may include limited identifiers under HIPAA. Of note, the code itself may not contain identifiers such as subject initials or medical record number.

Protocol 7: (c)	Protocol **Procedures to Maintain Confidentiality: 10 (h)**
• Will the participant's identity be coded? Will the codes to identify participants be stored with the data?	• If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.

Protocol 8: 1-4 5 6 7 8 9 10 11 12 13 14

Protocol 8: (a)	Protocol **Risks: 8 (a)**
• Does the research propose greater than a minimal risk to participants?	• PI's evaluation of the overall level of Risk. Please check one: minimal or > minimal.

Protocol 8: (b/c)	Protocol **Risks: 8 (b)**
• Indicate if any of the following risks are involved in this study. • Of the risks and discomforts identified above, note the likelihood (probability) and degree (magnitude) of potential harm.	• Describe all known risks or discomforts associated with study procedures whether physical, psychological or social (e.g., pain, stress, invasion of privacy, breach of confidentiality) noting probability and magnitude of potential harm. Specify the risks(s) associated with each research procedure or test.

Protocol 8: (d)	Protocol **Risks: 8 (c)**
• Discuss measures that will be taken to minimize risks or discomforts to subjects.	• Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).

Protocol 8: (e)	Protocol **Risks: 8 (d)**
• Explain how unanticipated negative outcomes /experiences or serious adverse events will be managed.	• How will subjects be assessed for unanticipated problems?

Protocol 8: (f)	Protocol **Risks: 8 (e)**
• Discuss plans for reporting unanticipated problems, involving risks to subjects or others, or serious adverse events to the IRB. (This item applies to all types of research.)	• Is there a plan to monitor study data for subject safety?

Protocol 8: (g)	Protocol **Recruitment: 7 (g)**
• Describe plans for provision of treatment for study-related injuries and how costs of injury treatment will be covered.	• Who is responsible for costs incurred due to injury/harm?

Protocol 9: 1-4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14

Protocol 9	Protocol **Drugs and Devices: 14**
• Does your study involve the use of a combination drug/biological product and device? If yes, you must complete and submit the Medical Device Form.	• See Image Below • *Note*: Drugs and devices are now included as separate items

Protocol **Drugs and Devices:**

14. Drugs and Devices

Drugs	Add | Delete
Please click on Add to add Drugs	

Device	Add | Delete
Please click on Add to add Device	

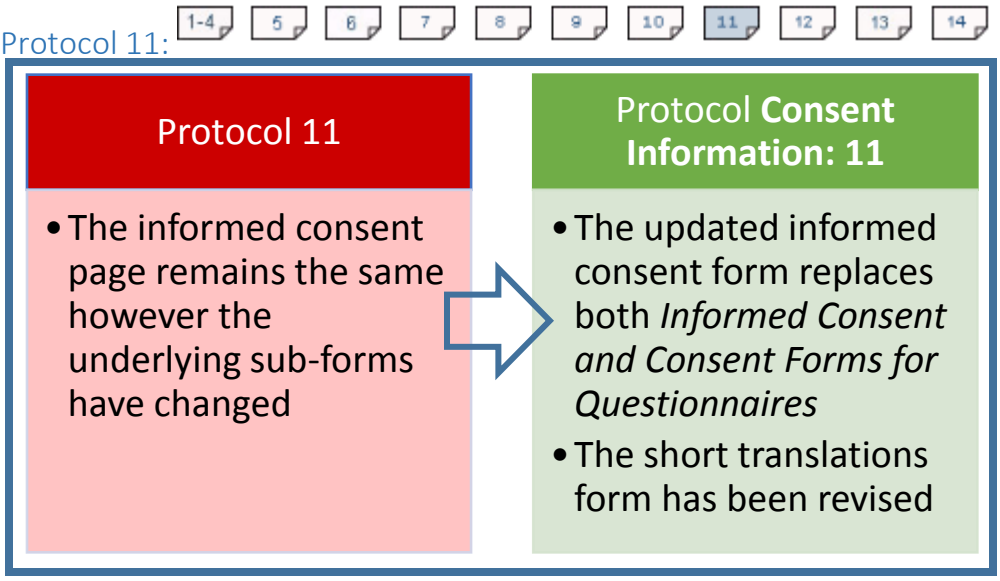
Protocol 10: 1-4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14

Protocol 10	Protocol **Benefits: 9**
•Indicate the type of benefit that may result from participation. Consider psychological or emotional benefits, learning benefits, learning benefits, physical benefits and discuss if participant will benefit directly or if the benefit is largely to gather generalizable knowledge or provide scientific or social information on a topic that may benefit society. DO NOT OVERSTATE the benefit.	•Discuss any potential benefits that would justify involvement of subjects in this study. •Direct benefits to subjects •Indirect benefits to society

New Fields

- 9(b): Explain how the potential benefits justify the potential risks involved in participation in this research

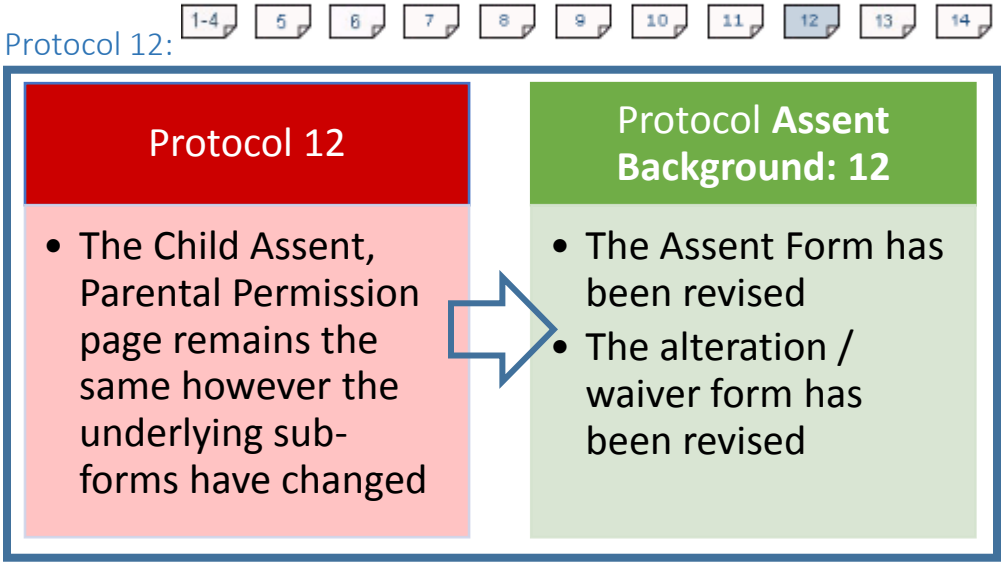
Protocol 11:



New Fields

- *Waiver of Documentation of Informed Consent* can now be uploaded as an Information Type in the Informed Consent field.

Protocol 12:



Protocol 13:

Protocol 13	Protocol (HIPAA): **13**
•Does the study involve the use of PHI from an University of Notre Dame covered entity? •Does the study involve use of Protected Health Information (PHI) from a covered entity outside of University of Notre Dame (i.e. another organization or institution)? •Does the study involve use of a "limited data set"?	•Research which involves the use of de-identified data is exempt from HIPAA requirements. In order to be de-identified data. NONE of the subject identifiers listed below can be collected, used, reviewed, recoded, accessed or disclosed. Please review the following list and indicate if any of the information will be collected from any medical records for the purpose of this research project. •The questions have been removed, as they are incorporated on the HIPAA Waiver •<u>It is important to note that the HIPAA Waiver must now be uploaded in</u> **Protocol Information: Attachments tab**

New Forms – 1

Protocol **Conflict of Interest**

15. Potential Conflict of Interest

Conflict of Interest and the definitions related to the Conflict of Interest Policy and the following questions, please refer to the Help Screen.

Conflict of Interest: Please check Yes or No for each item below.

a) Yes No — Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?

b) Yes No — Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

c) Yes No — Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

d) Yes No — Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

e) Yes No — Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

f) Yes No — Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

Significant Financial Interest: Please check Yes or No for each item below.

g) Yes No — Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

h) Yes No — Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

Yes No — If either g or h are Yes, is there a management plan in place?

Yes No N/A — If you have a management plan, is the COI being managed related to human subject research and/or this protocol?

Minimizing Risks and Disclosure to Subjects

i) Yes No N/A — Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

j) **What steps, if any, have you taken or will you take to manage the conflict of interest and minimize the risks associated with any actual, potential or perceived conflicts of interest arising out of this research?**

If you checked Yes to any statement (a-h, except f) above, please identify the research team member(s) below and provide details concerning the potential conflict of interest.

Research Team Member(s) with Potential COI Add | Delete

Please click on Add to add Research Team Member(s) with Potential COI

New Forms - 2

Protocol Information: Subject Population 5(k)

a. **Where is the research to be conducted?**

b. **Describe the cultural norms with respect to research, individual autonomy, consent, age of majority, etc. in this setting**

c. **Are there privacy/confidentiality concerns unique to the country/region?** Yes No

If yes, describe.

Consent

a. **Describe how consent will be obtained from participants/surrogates/legally authorized representatives:**

Note #1: If children will be included in the study, please complete a "Request for Inclusion of Children" form (https://research.nd.edu/our-services/resource-library/)
Note #2: Any request for a waiver of the requirements for informed consent must include completio of a "Request for Waiver of Consent" form (https://research.nd.edu/our-services/resource-library/)

b. **Describe how the investigators will ensure that participants understand the nature of the research**

c. **Describe the steps that will be taken to ensure that potential participants understand that participation is voluntary**

d. **If consent forms are to be used with persons not fluent in written English, how will translations be obtained?**

Note: All translated consent forms, assent forms, recruitment materials must be submitted to the IRB. Any request for a waiver of the requirements for documentation of informed consent must include completion of a "Request for Waiver of Consent Documentation" form (https://research.nd.edu/our-services/resource-library/)

Language

a. **What is the primary language(s) in the region(s) where the research will be conducted?**

b. **Are the investigators who will be interacting with participants fluent in the primary language of the subjects?** Yes No
If no, describe the steps that will be taken to ensure that participants and investigators are able to communicate with each other:

Expertise and Consultation

a. **What are the investigator's qualifications to conduct research in this setting (Include hov knowledge of local customs, culture, laws and experience with the type of research desc for the study)?**

b. **Will the investigator be collaborating with local persons (e.g., researchers, universities, community leaders, etc.)?** Yes No
If yes, describe:

c. **Will this research be reviewed by a local IRB or ethics committee?** Yes No

If yes, describe how you will communicate and coordinate with the committee:

How will you handle and report complaints, non-compliance and unanticipated problem

Please provide the contact information for the local IRB or ethics committee:

If no, do you have local/regional/national permission/certification to conduct research in the country? Yes No
If yes, describe.

If no, explain.

Export Control

a. **Will this research be conducted in a country under embargo or sanctions with regard to export control?** Yes No