Artificial Intelligence Human Subjects Research (AI HSR)
IRB Reviewer Checklist

Reviewer:		**Date Received:**	
Principal Investigator (PI):			
Project ID Number:			
Study Title:			

For studies involving Artificial Intelligence (AI) and Human Subjects, the IRB should review the IRB protocol application in full, per normal practice, using their standard reviewer checklist, ***in addition to*** the following the below AI Reviewer Checklist. For studies that meet Common Rule Exempt criteria, the IRB should conduct a Limited IRB Review to assess the extent to which data can be traced back to the individuals, now or in the future. If applicable, as part of the privacy and confidentiality assessment, the IRB should also ask the PI to provide the most recent Privacy and/or Terms of Use statements from any third-party platforms that provide data, summarizing and confirming agreement to abide by those terms.

Yes	No	N/A	AI RESEARCH Reviewer Protocol Checklist
			FOR ALL AI RESEARCH PROTOCOLS (to be used in conjunction with the general IRB reviewer checklist)
			I. Can it be reviewed by our IRB?
Yes	**No**	**NA**	**Description**
☐	☐		**Is the Study considered "Classified Research"?** If "yes", STOP. *Confirm with your legal department if permitted to conduct classified research.* **NOTE:** Even if the study is not "classified", studies involving controversial purposes such as research conducted for military or lethal purposes must be reviewed Full Board and confirmation of acceptability from the Institutional Official documented.
☐	☐		**Is your proposed device/model/technology used for health-related purposes?** **If no, explain:** Click or tap here to enter text.
			II. Description of Technology (usually found in the "Data Analysis" section of IRB Protocol
			List the model(s) being used in this project **(Example: XGBoost, Google Cloud TPU, Weka, scikit-learn, Light GBM, MLlib, etc.):** Click or tap here to enter text.
			Overall Purpose of Technology (check all that apply): ☐ Prediction Model (Risk prediction, etc.) ☐ Mining text records (e.g., using NLP to mine EHR) ☐ Record abstraction to identify specific patients with specific conditions ☐ Other: Click or tap here to enter text.
☐	☐		**Check "yes" if the technology is considered "investigational" or "no" if it is limited to clinical care (QA/QI)?** **If investigational, utilize your institution's Investigational Device checklist AND continue to answer below questions:** **What kind of technology is being utilized (check all that apply).** ☐ Algorithms / Machine Learning (AI/ML) ☐ Natural Language Processing (NLP) ☐ Deep Learning (example: Neural Networks) ☐ Unsupervised Learning ☐ OTHER: Click or tap here to enter text.

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☐	☐		**METHODOLOGY:** **Does the technology have a transparent methodology?** **(Examples:** CRISP-DM, KDD, SEMMA, CPMAI, etc.) NOTE 1: a methodology may not be appropriate for the intended use, such as comparing a prediction model to a doctor's prediction) NOTE 2: Prediction modeling is not a methodology, it is a statistical technique using ML and data mining. ☐ Check if methodology is not relevant to AI
Adaptivity: ☐ Algorithm is locked (doesn't change over time) ☐ Algorithm is adaptive (learn in real time)			
Data to be collected ☐ prospectively or ☐ retrospectively (data that is, as of today, currently sitting "on the shelf") ☐ combination of both prospective and retrospective data			
Is the program intended to inform or to "drive" medical decisions? ☐ **"Inform"** means a medical decision must be able to be made (and confirmed) without the technology, but the technology can support the medical decision. ☐**"Driving"** decisions means it does not replace a provider's independent judgment. Makes personalized recommendations that the physician would act on			
III. AI HSR DETERMINATIONS			
(i) Is it *"Human Subjects" per federal definition*?			
☐	☐		**A. Does the technology require *collecting or using* data *from or about* living individuals?** (i.e., not deceased; the data assumedly is coming from people who are as of right now, currently alive) **If "Yes", may be HSR. Continue.**
☐	☐		**B. Does the study involve obtaining identifiable information about living [presumably currently alive] individuals?** ***Identifiable information*** *includes information about living individuals where the identity of the subject is identified or may be identified by the investigator or a third-party in a reasonable amount of time through reasonable efforts (e.g., combining large sets of data; connecting a YouTube account username, face, voice, etc. with other social media accounts). In this case, there is usually a common variable in the dataset that "links" the individual.* **If "Yes", may be HSR. Continue.**
☐	☐		**C. Does the study involve obtaining private information or Protected Health Information (PHI) about living individuals?** ***Private information*** *includes information about living individuals' behavior occurring in a context with a reasonable expectation of privacy (e.g., activities in one's home or classroom), and information provided with a reasonable expectation of privacy (e.g., medical records, school grades, personal posts or messages on social media or any other website where membership or special passwords/access privileges are required).* **If "Yes", may be HSR. Continue.**
☐	☐		**D. Does the study involve any *interactions* [such as communication, even if done virtually, directly or indirectly and/or via robots] (through surveys, interviews, tests, focus groups, observations, etc.)?** *Interactions include any communication or interpersonal contact (virtual or in person) between investigators and living individuals for the purpose of the study.* **If "Yes" to any above and (D), may be HSR. Continue.**
☐	☐		***E.*** **Does the study involve any *interventions*? For example, includes manipulation [managing or influencing] of a person, or a person's environment or condition (including advising on a course of action as a result of the AI output?** ***Interventions*** *include procedures by which the technology is used as a means of collecting data (e.g., venipuncture, interviews, focus groups, surveys, physical activities, etc.), manipulation of living individuals' environments that are performed for the purpose of the study, etc.* ***Example 1:*** *Asking participants to wear various sensors or be scanned by devices and/or have them perform various tasks to obtain physiological measurements (heart rate, blood pressure, retinal scans, gait,*

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			etc.) or biometric identifiers such as face, voice, fingerprint, etc. ***Example 2:*** *Using an ML Prediction Model, identify someone who is at risk and alter their treatment based on output/recommendations* Notes: Click or tap here to enter text." **If "Yes" to any of (A-C) and (E), study is HSR.**
(ii)			**Is it "*Research*" per federal definition?**
☐	☐		***1) If your project a "systematic investigation" including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?*** *(Study will usually h*ave a hypothesis or hope to answer a research question) ***If "No" to III(1) above AND "No" to (III)1-3 or 5, study likely not HSR.*** **If "Yes" to above,** Confirm investigator describes what the evolution of the algorithm will look like (how PI knows the study was successful)
☐	☐		**Generalizable: Is the knowledge obtained from this research designed to develop or contribute *generalizable* (i.e., to make the tech/knowledge widely applicable and/or available?) knowledge?** ***Example:*** Obtaining new knowledge about human behaviors (Ex: to model human behavior) via AI/ML or developing a new technology/software/device that can be used broadly.
IV.			**Purpose of Study:**
What is the technology's overall AIM in this specific protocol application? ☐ **ONLY Proof of Concept (POC):** POC meant to illustrate a concept in a "almost real" environment but does not get deployed into real-world. ☐ **Pilot:** Real-world project uses technology in protected environment but NOT for use in real-world production. ☐ **Real-world Pilot:** Interventions/treatment may run in parallel with the training and re-training of model? ☐ A combination of one or more above (check those applicable) **Note:** If the product is investigational, even if it isn't intended to be used outside of your immediate institution, the project will still be considered research.			
☐	☐		Is the study intended (wholly or partially) for the development of a product?
☐	☐		**Is the technology being used in a device?** If "yes", confirm application describes ***why*** the product is being made. For example: for clinical use; for behavioral/therapeutic purposes; for diagnostic purposes; etc.
☐	☐		**ROLE** of the AI in meeting the aims of the study: Confirm application describes (generally) the portion of the project that requires AI. In other words, is the aims of the study entirely dependent upon the AI? Confirm this is included in the aims or objectives (I.e., transparent on criteria for success) **NOTE:** AI/ML that is utilized in invasive procedures will have higher risk and must go through clinical trials first; While AI that is utilized in non-invasive procedures (such as chatbots, CDS/PDS, etc.) may pose less risk than invasive technologies, these non-invasive technologies may not be minimal risk. IRB must consider the ***functionality risk*** as well as other risk (see ethical considerations below) of the software/AI in devices outside of the technology itself.
☐	☐		**Is the technology provided by a sponsor/client/vendor?** If "yes", what is the contractual obligation? ☐ Research ☐ Product evaluation ☐ Quality Improvement/Quality Assurance ***Research Example:*** *Developing algorithms to run in a device/product that could effectively assess stool and urine samples for various medical conditions.* ***Product Evaluation Example:*** *Using AI to compare one non-investigational device to another to see if they are equal or better.*

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			QA/QI Example: Using AI to identify hospital admission rates and how long people wait before getting seen in an emergency room to improve their workers performance and/or services. **NOTE:** Industry sponsored typically require additional considerations such as ICOI/COI, and liability; AI may have institutional/legal implications in regard to liability. See ICOI/COI and Ethical Considerations sections below for more information. Patents and ownership will also be an issue to be resolved under their own ancillary committees.
V.			**FDA / OHRP Distinctions**
☐	☐		**Is the intention for the technology developed/used in this specific study to be made available to the US market? (i.e., made available for use outside of your institution)**
How is the technology being used? ☐ Clinical Decision Support Tool ☐ Patient Decision Support Tool ☐ Diagnostic ☐ Treatment			
☐	☐		**Has there been a risk determination made?** **If yes, by who (check all that apply)?** ☐ **IRB** Finding & Rationale: Click or tap here to enter text. ☐ **FDA** Finding & Rationale: Click or tap here to enter text. ☐ **Sponsor** Finding & Rationale: Click or tap here to enter text. ☐ **Investigator** Finding & Rationale: Click or tap here to enter text. ☐ **N/A** Explain (Example: Study is an Exempt Device per 812.2(c)): Click or tap here to enter text.
☐	☐		**Requires FDA Oversight (Yes or No)** ☐ Medical Device exempt from FDA oversight (per Cures Act Section 520)(o)) ☐ Does not meet federal definition of Medical Device
☐	☐		**Does ANY aspect of this study, including long term goals, involve a *potential need* for findings to be submitted to the FDA or the results of the research* intended to be submitted to the FDA as part of an application for a research or marketing permit?** Example: Study involves Software as a Medical Device (SaMD) such as mobile medical apps, software/technology (AI/ML), etc. that will contribute to the treatment, cure, mitigation, diagnosis, or prevention of a disease or condition? ***NOTE:** The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for this definition. Any FDA-related studies must comply with both FDA regulations and DHHS/OHRP requirements.*
VI.			**Institutional and PI Financial Considerations (ICOI / COI)** **Any conflicts should be treated like any other ICOI/COI per institutional procedures and policies.** *(This information is collected to guide in COI disclosures in ICF, if applicable)*
☐	☐		Is the Algorithm/Product/Software intended to become Proprietary? Will it be utilized only within the PI's clinic? Regional hospitals? Nation-wide? Can/will it be commercialized outside of your institution?
☐	☐		**Will the technology developed by study team result in:** Payments from the transfer (licensing) of technology created at your institution or to an entity, including royalties, milestone payments, and other licensing fees; in (i.e., ownership of) a company (publicly or non-publicly traded) resulting from the transfer of this technology or from direct investment;
☐	☐		**Will the technology developed by study team result in:** Gifts, including gifts-in-kind of goods or services, from a potential sponsor (i.e., a commercial company), from a philanthropic unit of the sponsor, or from an individual affiliated with a sponsor;

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☐	☐		**Will the technology developed by study team result in:** An institutional official receiving payments, honoraria, royalties (including those from your institution), equity, options and warrants, company positions (e.g., board directorships and/or management), or gifts?
☐	☐		Is the Sponsor funding research at your institution or manufactures products to be studied or tested at your institution, or under its auspices?
☐	☐		**Sponsored Research (check all applicable):** ☐ **Sponsor-Investigator Research:** Your institution is developing the technology ☐ **Industry Sponsored Research:** Study team is using technology that is industry/commercially sponsored ☐ **Other Sponsored Research:** Study team is using technology under investigation by a federal sponsor, or other federal contract/institution. (Federal contracts may affect future use)
☐	☐	☐	Any contractual obligations with sponsor? If so, describe (this is usually found in the Scope of Work (SoW)/Exhibit A in the contractual agreements): Click or tap here to enter text.
VII.			**Ethical Considerations (Belmont Report) & Technology Risk Assessment (TRA) ((45 CFR 46.111(a)(2); 21 CFR 56.111(a)(2)))**
A)			**Respect for Persons: Participants have enough information to make an informed decision (or the IRB grants a waiver of informed consent and HIPAA Authorization. The following information should be considered in this assessment:**
	(i)		**Data Integrity (a)(b) and (c):** These considerations would be more appropriately addressed in the Risk Mitigation Section of the IRB Application (or under an addendum).
☐	☐		**Data Integrity (a):** Confirm the source and characteristics of data used to train the model clearly explained (e.g., What datasets are going to be utilized? Will datasets be combined? Why it is being combined?)
☐	☐		**Data Integrity (a)(i):** Confirm the model being developed is in this specific protocol application or clarify if it developed in a previous project and/or at an external institution. If developed in a separate project, confirm that model was cleared or approved by the FDA and under what conditions that model was cleared or approved (if applicable). Confirm if study team will be modifying that model in any way or using it for purposes different from what it was originally designed, cleared, or approved for. *(This information is for transparency and can also be included in the ICF, if applicable)*
☐	☐		**Data Integrity (b):** Confirm the application describes the following: • Does the application describe what features of data will be used? For example, a project captures broader populations but individual measurable properties and/or characteristics of a phenomenon being observed contain potential PII/PHI? Such as age, gender, height, weight, gait, voice or facial recognition, etc.) • Does the collection of data involve the use of Application Programming Interface (API) to provide access to the data of an application or operating system. • Does it involve scraping? (Scraping uses automated programs to collect data, faces, voices, etc. from a website in a methodical way). *Note: This may affect your institution's research institution's policies and/or regulations. The institution's Technology Risk Assessment (TRA) may be required.*
☐	☐		**Data Integrity (c):** Confirm application describes what will happen to the data when this specific project is complete. **Example:** Will the data be destroyed or deidentified? How will it be de-identified?
☐	☐		**Explainability / Human interpretability (XAI/XML):** Is the protocol written in a way that ensures AI applications are able to "explain" why a decision was made. IRBs should consider risk if any action or output is acted on autonomously, especially if such action might affect humans health or wellbeing. *I.e., is the protocol written so that the PI/research team can examine the input features that were most important in making the decisions it made? PIs should explain how they are using the best available interpretability technology and confirm commitment to updating this as technology improves.*

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			NOTE 1: Oftentimes, the researcher conducting the study is not familiar with the AI technology or has limited background. In such a case, the IRB needs to consider how the study team will be communicating about these black box issues and how they will update the tech (and the IRB and/or FDA, as applicable) with any needed changes. NOTE 2: These considerations would be more appropriately addressed in the Risk Mitigation Section and not an addendum as they are more directly linked to the safety and efficacy of the "device" (software/tech).
☐	☐		**Training and Monitoring:** **Confirm application describes continuous training/iteration and monitoring of model** (to accounting for data changes or model drift over time)**.** **If no re-training, explains why:** Click or tap here to enter text. **Note:** this may require continued IRB oversight
☐	☐		**Transparency to Participant:** Confirm application describes if the participants be notified if an AI product is part of their care and what data that was trained on?
B)			**Justice: No group bears the burden of testing (or being the test of) new technologies while other groups reap the rewards**
☐	☐		If the project enrolls people into interventions, confirm the study design and procedures (including recruitment) ensure equitable selection. **NOTE:** If the project enrolls only data from people, confirm the source and characteristics of data used to train the model are clearly explained (If looking at cancer, the data should not be limited to a certain gender, race, ethnicity, or age, etc. unless the study is specifically targeting that population. For example, lung cancer in non-smoking Asian American women).
☐	☐	☐	**Vulnerable populations (this should be covered in the main IRB Protocol Application)** If the study requires targeting vulnerable populations: ☐ Justification is adequate (see above for special considerations). ☐ Justification is ethical (based off standard Belmont Report, including for data-only AI projects).
☐	☐		**Benefits and Technology Access:** **Confirm protocol:** ☐ Describes who, ultimately, is benefiting from the development and use of this technology? Will it be equally accessible or limited to only a select group or entity? ☐Who is benefiting from this? Describes how findings and general knowledge benefit the populations of which the data originated. If the benefit limited to a specific population or setting, justifies. Explain: Click or tap here to enter text. For example, will a novel technology, should it be proven successful, be available for wide use? This can be problematic for federally funded projects in which findings are expected to be shared. This can also pose ethical concerns for making technology available to people who could benefit from it but can't afford it.
C)			**Beneficence: In order to adequately assess the risk benefit ratio and confirm the risks of participation do not outweigh the potential benefits of participating in the study; consider the following:**
☐	☐	☐	**Dual Use** Has the study team considered how the product is intended, or could potentially be used after the research is completed (i.e., who will use the system after the research is complete and in what context?) **Consider:** Is there dual use potential? If so, have the specific dual use concerns risks been adequately addressed? Note: Most commonly found in facial recognition technology, decision-making algorithms, and autonomous weapons systems **See NIH policies on Dual Use (DURC) and the Human Brain Project's Dual Use Suggestions**
☐	☐	☐	**Monitoring Plan:** Confirm plan for monitoring how the AI is being used is clearly described.

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			☐ Describes what possible mistakes it could make, and plan to address UPs such as if the AI begins to make harmful mistakes. ☐ Describes adequate controls in place for preventing abuse now (during the research) and after the research is complete. ☐ Describes iteration requirements and plans for continuous monitoring and evaluation of the data (retraining model); if not needed explained why? (example: the real-world environment doesn't change) [Should be in "duration of study" and "data analysis" section].
☐	☐		**Algorithmic risks addressed: in the Risks section of the IRB Application, the PI should:** ☐ Describe how the project could go wrong? Example: bias in algorithm, etc. ☐ Describe how technology could be abused (e.g., nefarious use, dual use, etc.)? ☐ Describe how algorithmic decisions do not create discriminatory or unjust impacts when comparing data across different demographics or affected communities and individuals.
☐	☐		***Transparency:*** Confirm protocol describes how the model(s) function; the process and role of the model's output in final decision making are explained and comprehensible to the participants (e.g., is the "black box" addressed?). ***Ask about un-black-boxing:*** *"What historical data is used to train this tool? How is the data adjusted for the target patient population?*
☐	☐		Application describes variables used in the model (and if PHI/PII is included)
☐	☐		***Accountability:*** Confirm protocol describes how technology is designed and implemented in publicly accountable ways, such as an obligation to report; explains and justifies specific decisions as well as mitigates negative impacts and potential harms. ***NOTE: This can be described in risk/benefits section when prompted to describe how risks will be mitigated.***
VIII.			**Privacy & Confidentiality ((45 CFR 46.111(a)(7); 21 CFR 56.111(a)(7)))** **(Some may be overlap with standard IRB review process; Confirm AI specific items should be addressed)**
☐	☐	☐	Consent and/or application clearly explain limitations of privacy and confidentiality (e.g., due to utilization of external vendor services such as Google, Amazon, etc.)
☐	☐	☐	Data use and Terms of Use (ToU) requirements of third-party sources such as Facebook, Instagram, Twitter, dating websites, YouTube, LinkedIn, other social media websites, etc. have been reviewed by PI and provided to IRB for review. **Note:** PI should confirm adherence to these requirements and acknowledge these are not the same as "informed consent" for research purposes. *Check N/A if there is no third-party involved in data collection or storage*
☐	☐	☐	Consent and/or IRB application describe if (and how) data will be combined with other datasets, and the possibility of re-identification and/or obtaining additional information on them, why this information is needed, where they are obtaining this information from *Check N/A if there are no plans on merging the data set or specimens with additional/external data sets*
☐	☐	☐	**Other online survey platforms and/or software** (e.g., Google forms, Qualtrics, survey monkey, etc.): Consent and application clarify if/how third parties may collect participants online behavior and history (via cookies or other tracking systems), if info might be sold to third parties, etc. *Check N/A if there is no third-party involved in data collection or storage*

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☐	☐	☐	**Data Minimization:** Justification for each datapoint is included: only includes the bare minimum necessary in order to meet the study's purpose (absolutely necessary, and that the study goals could not practicably be achieved without that specific data). ***Note:*** *for studies that meet Exempt criteria, this should be done through a Limited IRB Review*
VIII (A). Other Confidentiality Considerations: Audio/Visual/Biometric Identifiers:			
☐	☐		Consent and application describe how participant audio/visual/biometric (voice, finger, facial, etc.) data is used, stored (coded, transposed, etc.), shared, destroyed/not destroyed, de-identified/not de-identified, etc.)
☐	☐	☐	Describes any reasonably foreseeable purposes in which participant data may be used in the future, how it will be shared, with whom it will be shared, how long it will be stored, when it will be destroyed *Check N/A if there is no plan to use data in future or share with anyone*
☐	☐	☐	If audio/visual/biometric data is to be used to determine a person's eligibility for, or access to a program, service, or opportunity, consent form and IRB application describes those risks *Check N/A if there are no biometric datapoints used to determine eligibility*
☐	☐	☐	Describes if audio/visual/biometric data will be combined with other data and why *Check N/A if no audio/visual/biometric data is collected*
IX.	**Misc. Considerations (may overlap with standard IRB review process)**		
☐	☐	☐	**Minors in research:** ☐ Adequate plan to ensure participants are 18 years of age or older. ☐ Adequate plan to ensure parental consent is obtained for minors. *Check N/A if no minors are involved*
☐	☐		**Community Input:** Has there been any input received from the relevant community that would have to adopt the technology, should it be found effective? Ex: if the tool would be used in Emergency Departments, has the study team conducted focus groups of these departments to get their feedback?
☐	☐	☐	**International:** If data collected or potentially could be collected internationally, the PI has adequate provisions in place to honor GDPR or other international regulations. *Check N/A if no international data is collected*
☐	☐	☐	**Future Modifications Considerations:** Does the Researcher foresee a possible need to modify the protocol in such short amount of time that convening an IRB or short turnaround times wouldn't be sufficient to successfully conduct the study? If so, can the protocol be designed broad enough so that those modifications can fit within the approved scope of the study? ***Example 1:*** *Allowing modifications to the algorithm or device so long as the general procedures and design of study are not altered and risks do not increase.* ***Example 2:*** *Any potential future updates that will be built upon algorithms are described*

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The AI HSR IRB Reviewer Checklist should be seen as an ongoing process, with future revisions of the recommendations based on comments, critique and new evidence. We welcome translations into other languages and extensions to other novel technology reviews.

Note: We ask anyone intending to use the AI HSR IRB Reviewer Checklist for further extensions, translations or other AI HSR-related work to contact the Author through etohconsulting.com. This will allow to coordinate efforts and to avoid duplication. The author of this AI HSR IRB Reviewer Checklist holds the copyright. Please, contact us if you wish to re-publish AI-HSR material in additional journals, books or other media.

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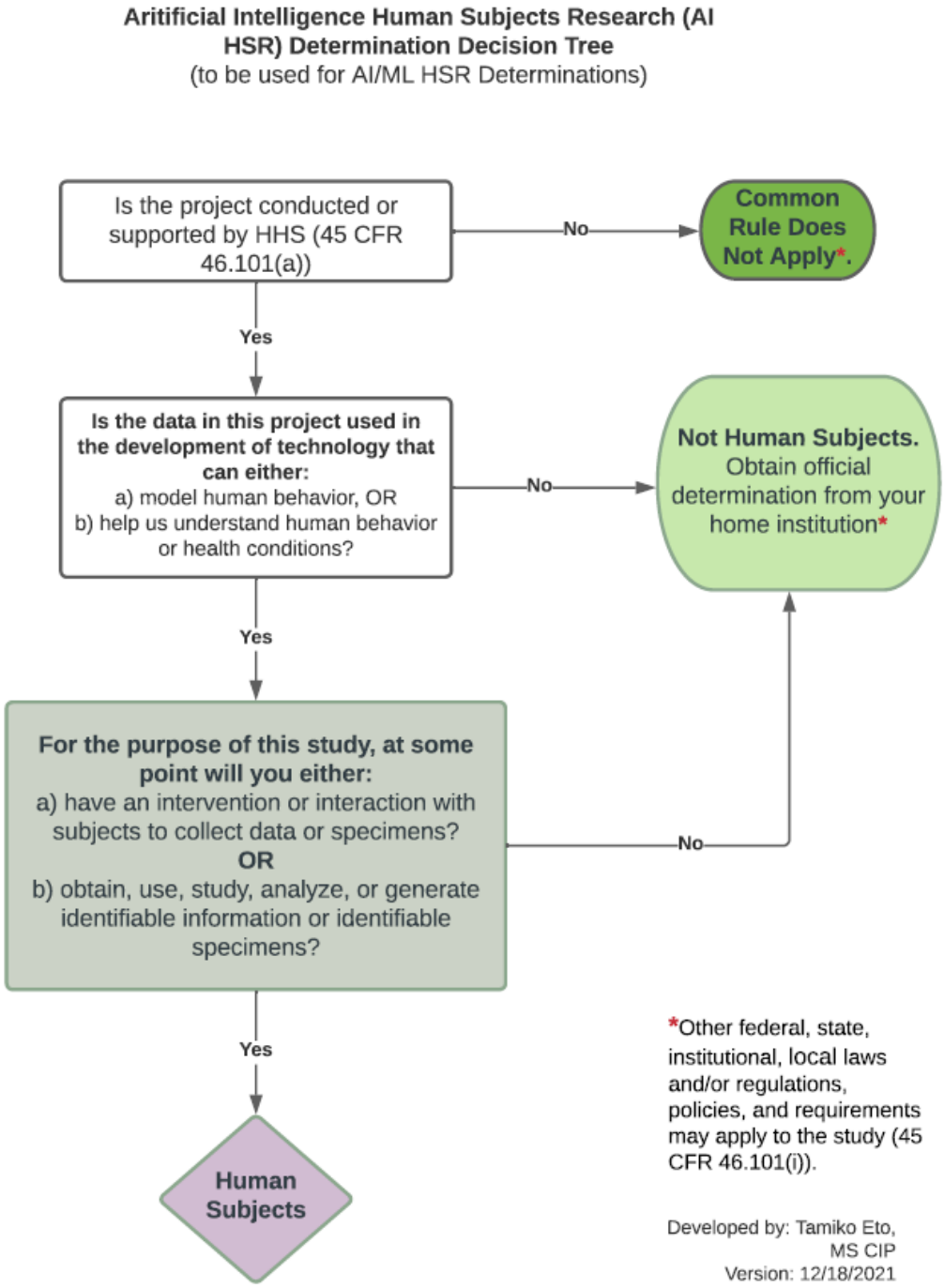

** There are two key factors in the term "generalizable knowledge": "designed to" and "including research development, testing, and evaluation". If a project includes multiple components and at least one of those components is designed to develop or contribute to generalizable knowledge, then the entire project is classified as research.*

If a project or program with discrete components involving data collection and analysis are designed with

different purposes in mind, some involving research and some not, but ***the purposes of the components are interrelated,*** *then all of the components are classified as research.*

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AI HSR Exempt Determinations Decision Tree