Comité Opérationnel d'Évaluation des Risques Enjeux Légaux et Éthiques
Demande d'Autorisation pour une Recherche impliquant des Sujets Humains

Nom du porteur du projet de recherche (PP) Pierre-Yves OUDEYER **No Tél.** +33 5 24 57 40 30
(permanent membre d'une équipe-projet Inria)

Nom du co-porteur du projet de recherche (co-PP) Thibault DESPREZ **No Tél.** +33 5 24 57 40 00

E-Mail du PP pierre-yves.oudeyer@inria.fr **E-Mail du Co-PP** thibault.desprez@inria.fr

Nom et adresse du contact,pour recevoir les documents d'approbation:

Catherine CATTAERT, Assistante d'équipe, Bureau B331, Inria BSO, 200 avenue de la vieille tour, 33405 Talence Cedex

Cocher la case s'il s'agit d'une recherche médicale ☐ ☐ou non médicale ☒ ☐

Equipe-projet(s) Inria impliquée(s) dans ce projet FLOWERS

Titre du projet Étude longitudinale sur l'impact de kits robotiques à l'école

Lieu de l'étude Lycées partenaires (*cf* annexe 5) + Inria BSO

Source de financement du projet: Projet e-fran PERSEVERONS

Numéro du projet :

Noms d'autres agences nationales ou européennes fournissant un financement ou un autre support à cette recherche :

Population cible: La population concernée par cette étude inclut (cocher toutes les cases appropriées):

☒ Internautes
☒ Mineurs/enfants
☐ Fœtus humains/Bébés
☐ Femmes enceintes
☐ Prisonniers
☒ Étudiants
☐ Personnes ayant un handicap mental
☐ Personnes ayant un handicap physique
☒ Autre : préciser Enseignants

Type d'évaluation (Optionnel): Vous pouvez proposer que votre recherche soit exemptée d'évaluation, évaluer de façon expresse ou régulière en cochant la case correspondante ci-dessous. En cas de proposition d'exemption, lister les numéros de catégories d'exemption (à fournir explicitement).

☐ **Exemptée-Lister la ou les catégories d'exemption** ***Ou*** ☐ **Expresse** ***Ou*** ☐ **Régulière**

Si vous proposez l'exemption, décrire brièvement la ou les raisons d'exemption:

Date **Signature du Porteur du Projet**

Date **Signature du Co-Porteur du Projet**

Date **Signature de l'étudiant chercheur**

Date **Signature du Directeur du Centre Recherche INRIA**
Nom :
Titre :

Important information: terms in this application are 'inherited' from medical research but are also applicable to non medical (or online) research including measurement studies, security and privacy related topics.

Protocol Application

I. Resources

a. Qualified staff.

Please state and justify the number and qualifications of your study staff.

- Thibault DESPREZ (doctorant équipe FLOWERS INRIA)
- Pierre-Yves OUDEYER (directeur de l'équipe FLOWERS INRIA)
- Didier Roy (chercheur équipe FLOWERS INRIA)

b. Training.

Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.

Pour nous assurer que toutes les personnes participant à la recherche sont informées du protocole, l'établissement scolaire à signer un contrat de collaboration (*cf* annexe 3) avec le projet Poppy Éducation où est défini un enseignant référent. Ceci permet d'entretenir une relation directe entre les membres du projet et les établissements. Par ailleurs ces enseignants seront invités à participer aux réunions d'avancement mensuelles, auront accès au compte-rendu des réunions, au calendrier prévisionnel, etc et ils seront informés en permanence de l'évolution du projet via un suivi mail.

c. Facilities.

Please describe and justify.

Tests réalisés en ligne via la plateforme de sondage sécurisée proposés par Inria (https://sondages.inria.fr/)
Les bases de données seront stockées de manière chiffrée, en local sur la machine du doctorant (Thibault Desprez) ; en ligne sur la plateforme de partage sécurisé Inria (http://partage.inria.fr/) ; et ceci en accord avec la CNIL et sa commission d'homologation de sécurité. (*cf annexe 4)*

d. Sufficient time.

Explain whether you will have sufficient time to conduct and complete the research. Include how much time is required.

Activité réalisée dans le cadre des enseignements d'informatique dispensé dans les sections ICN (Informatique et Création Numérique) et ISN (Informatique et Sciences du Numérique) au lycée (entre 1 et 3 h / semaine). Ou dans le cadre de sessions ponctuelle hors temps scolaires. Le projet est monté pour un minimum de 3 ans (sept 2016 à juin 2019) ; les phases d'évaluations et d'analyse s'alternent au rythme des vacances et des années scolaires. Ceci permet d'itérer rapidement plusieurs variations des expérimentations assurant leur robustesse à fournir des données pertinentes et la richesse de leur interprétation. Ceci permet également d'obtenir des résultat dès les premières itérations. De plus, cette temporalité s'intègre parfaitement dans le planning de thèse associé à ce projet.

e. Access to target population

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

Dans le cadre du projet Poppy Éducation, ont été recrutés des établissements secondaires (lycées) de la région Nouvelle Aquitaine avec un focus sur les filières ISN et ICN. Ce recrutement a été effectué en contactant directement les enseignants des spécialités et de la région visées. Un appel plus général a également été diffusé sur le web. Un effet de «bouche à oreille» a permis de compléter la liste des établissements volontaires à participer au projet.

f. Access to resources if needed as a consequence of the research.

State whether you have medical or psychological resources available that participants might require as a consequence of the research when applicable. Please describe these resources.

Les élèves, parents et enseignants, peuvent revenir vers l'administration du lycée, l'université de Bordeaux (en sa qualité de pilote du projet e-Fran PERSEVERNOS), le rectorat, la DANE, Canopé, ou Inria (en leur qualité de membres du projet e-Fran PERSEVERNOS)

g. Lead Investigator or Coordinating Institution in Multi-site Study.

Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

i. Chef de coordination : Thibault DESPREZ
ii. Communication avec les autres sites : réunions d'avancement régulières, mails, compte-rendu d'avancement.
iii. Documentation des communications avec les autres sites : weekly-report, compte-rendu des réunions.
iv. Planification de communication en cas de litige avec l'étude auprès des volontaires, résultats négatifs modifications de protocoles etc. : réunion d'avancement.

II. Protocol Information

1. Purpose

a) In layperson's language state the purpose of the study in 3-5 sentences.

Les technologies robotiques et numériques sont souvent présentées (notamment dans le milieu de l'éducation) comme naturellement attractives et re-motivantes. Hors, aujourd'hui, aucun résultat scientifique ne permet d'affirmer cela et il semblerait qu'il existe également un amalgame entre ces technologies et « les nouvelles technologies » qui, par leur côté novateur, suscitent effectivement une forme d'attrait inconditionnel. De plus dans le contexte de l'intégration des sciences numériques dans les programmes scolaires officiels, il devient indispensable d'évaluer les impacts qu'ont ces outils technologiques et les savoirs qu'ils véhiculent.

b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

- Évaluer l'utilisabilité du kit robotique pédagogique Poppy ErgoJr
- Évaluer l'engagement et la persévérance dans l'utilisation de ce kit
- Évaluer l'appropriation du kit par les enseignants
- Évaluer les connaissances et compétences acquises par les élèves et l'enseignant
- Évaluer les représentations qu'ont les utilisateurs sur les sciences du numérique
- Évaluer les impacts globaux sur la scolarisation de l'élève
- Comparer ces évaluations en fonction de la morphologie du kit proposé

2. Study Procedures

a) Describe all the procedures. Are the research procedures the least risky that can be performed consistent with sound research design?

Cf document de présentation du protocole

b) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.

Des enregistrements (photos, vidéos, audios, log) pourront être effectués pour, en faire, soit une analyse descriptive dans le cadre des expérimentations ; soit les diffuser lors de meetings de plusieurs types: colloques, réunions, conférences, etc à visée scientifique en tant qu'illustration des résultats ; formation, forum, réseaux sociaux, etc, à visée de diffusion et de médiation en tant qu'illustration de la pratique des activités . Pour chaque prise de vue, une autorisation nominative (mentionnant les usages précis du contenu) sera demandée. Sans cette autorisation, les visages seront floutés ou les enregistrements supprimés.

c) ~~State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 9). Submit a debriefing script (in section 12).~~

3. Background

a) Describe past experimental and/or clinical findings leading to the formulation of the study.

Cf document de présentation du projet (contexte et objectifs).

4. Subject Population

a) State the following: (i) the number of participants expected to be enrolled at INRIA research center(s); (ii) the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, teachers, government officials) and the reasons for using such participants.

i. Aucun participant ne sera recruté dans un centre INRIA
ii. Entre 5 et 20 participants par établissement (x10) par an (x3) soit entre 150 et 600
iii. Élèves du secondaire et leurs enseignants (ou personnel encadrant)

b) State the age range, gender, and ethnic background of the participant population being recruited.

Élèves entre 12 et 20 ans, 50% de filles, 50% de garçons, pas d'ethnie particulière.

c) ~~State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.~~

d) ~~If women, minorities, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).~~

e) ~~State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it.~~

f) Describe how potential participants will be identified for recruitment (e.g., response to an ad, classroom recruitment, word of mouth, and letters mailed home). Describe recruitment procedures. Attach recruitment materials in Section 12 (Attachments).

Le projet Poppy Éducation a fourni une liste d'une dizaine d'établissements scolaires équipés de kits robotiques ErgoJr et déjà volontaires pour participer à l'étude (recrutement décrit en section 1.e) . Le projet e-Fran PERSEVERONS, via La DANE (partenaire du projet), a effectué (via les mailling listes officielles) une proposition d'équipement à l'ensemble des lycées de la régions Nouvelle Aquitaine, une dizaine d'établissements a répondu à cette offre et pourront potentiellement intégrer l'étude.

~~g) If subject population is composed of Internet users (online research), state how you will select them.~~

h) Payment. Explain the amount and schedule of payment, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participant and that they do not constitute undue pressure on the participant to volunteer for the research study. Include provisions for prorating payment.

Pas d'indemnisation, le recrutement ne se fera que sur le volontariat.

i) Costs. Please explain any costs that will be charged to the participant.

Pas de frais, le matériel (kit robotique ErgoJr, valeur 320€ pièce) est mis à disposition. La quantité varie selon les besoins des établissements et atteint en moyenne 6 kits par établissement.

j) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.

Durée totale : 36 mois

5. Risks

a) For the following categories, describe the potential risk(s) and estimate their frequency, severity, and reversibility.

- *Physical well-being.*
- *Psychological well-being.*
- *Political.*
- *Economic well-being.*
- *Social well-being.*

Aucun risque d'atteinte dans l'une de ces catégories.

b) ~~En case of research concerning subjects outside France, describe qualifications/preparations that enable you to estimate and minimize risks to subjects.~~

c) ~~Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.~~

d) ~~Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed participant.~~

*e) **Data Safety and Monitoring Plan (DSMP).***

Describe the following:

- *The type of data or events that are to be captured under the monitoring plan.*

Étude longitudinale:

→ Questionnaires en ligne:
  - compétence en informatique / logique / mathématique (*cf* concour CASTOR) pour les élèves
  - utilisabilité et expérience utilisateur avec le kit robotique pour les élèves et enseignants
  - motivation globale pour les élèves
  - état de représentation de "la pensée informatique" chez les élèves

→ Fiche de renseignements (anonymisée par le numéro d'étudiant, (*cf* annexe4 - dossier CNIL)
→ Observation de l'enseignant
→ Résultats scolaires globaux (notes, observations, redoublement, réorientation)
→ Engagement et accompagnement des enseignants

Étude ponctuelle:
→ Fiche de renseignements (exclus "nom" "prénom")
→ Enregistrement vidéo et audio
→ Grille d'observation
→ *log* (clic souris, nombre d'instructions envoyées au robot, etc)

- *The Monitoring Entity (ME) that will be responsible for monitoring the data collected, including data related to unanticipated problems and adverse events, and their respective roles (e.g., INRIA D2T representative, INRIA Computer center, investigator, sponsor, independent monitor, CNIL or some other entity). If there is no ME, then the Protocol Director (PD) is responsible for this function.*

Une demande à la CNIL est en cours impliquant une homologation de sécurité sur le recueil, le stockage des données et le degré de sensibilité de ces données pour les sujets (*cf* annexe4 - dossier CNIL)

- ~~*If the ME is not the D2T representative or the PD, provide information about the ME's scope and composition, e.g. information about each members' experience or area of expertise.*~~

- ~~*The time frames for reporting adverse events and unanticipated problems to the ME.*~~

- ~~*The frequency of assessments of data or events captured by the monitoring plan.*~~

- ~~*Specific triggers or stopping rules that will dictate when some action is required.*~~

- ~~*As appropriate, procedures for communicating to the IRB, the study sponsor, and other appropriate entities the outcome of the reviews by the ME.*~~

Every year, the ME will provide a report to the IRB

Select One:
☒ This protocol will not utilize a Monitoring Entity. I understand that as Protocol Director, it is my responsibility to assess events and new information, and to report to the IRB as specified in the guidance. (*Need to provide the list of events and Information that require Prompt Reporting to the IRB*).

☐ This protocol will utilize a Monitoring Entity. I understand as Protocol Director, it is my responsibility to review reports from the Monitoring Entity and to report to the IRB those identified as unanticipated problems involving risks to participants or others according to the criteria of being unexpected, related, and harmful, as specified in the guidance.

f) Children's Findings

If children are involved in your research, please select the regulatory category below that your research falls under and provide the necessary rationale for this determination.

The IRB may determine that the permission of one parent is sufficient, or that permission of two parents is required, in which case the investigator must obtain the permission of both parents unless one parent is deceased, unknown, incompetent, not reasonably available or only one parent has legal responsibility for the care and custody of the child.

☒ *Research not involving greater than minimal risk. The research must present no greater than minimal risk to children and adequate provisions must be made for soliciting the assent of the children and the permission of their parents or guardians. Please provide rationale for the above statement.*

☐ *Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The research presents more than minimal risk to children, but holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being. Please provide*

rationale that: (a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

☐ *Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Research that presents more than minimal risk to children that does not hold out the prospect of direct benefit for the individual subject, or is not likely to contribute to the well-being of the subject. Please provide rationale that: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and (d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.*

☐ *Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Please provide rationale that: (a) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (b) the research will be conducted in accordance with sound ethical principles; (c) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.*

Rationale for above selection:

L'étude mise en place n'entraîne pas de risque pour les sujets.

6. Benefits

Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc.

→ Meilleur appréhension de "la société numérique". Développement des compétences en robotique et en programmation (et disciplines associées, e.g. mathématique, physique, logique, etc). Meilleur intégration de l'individu dans le milieu scolaire (par la pratique d'activités innovantes).
→ Compréhension scientifique des apports et challenges induits par l'utilisation d'outils numériques pédagogiques (notamment de type robotique) dans un environnement scolaire.
→ Impact sur les politiques d'éducation notamment sur le choix des outils disponibles en fonction des objectifs.

7. Privacy and Confidentiality

(*cf* annexe 2, 3 & 4: Consentement, Contrat de Collaboration, CNIL).

Privacy Protections

a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).

Signature d'un consentement éclairé (*cf* annexe 2)

Étude longitudinale:

→ Les établissements partenaires du projet Poppy Éducation et du projet e-Fran PERSEVERNOS (*cf annexe5* - liste établissements partenaires) fournissent une population d'enseignants et d'élèves pour participer à l'étude.
→ Pas d'interaction directe avec les élèves.
→ Relevé de données effectué via des questionnaires en ligne (hébergé sur la plateforme de sondage sécurisée de Inria)
→ Les données récupérées sont identifiées par le numéro d'étudiant de l'élève
→ Les enseignants n'ont pas accès à ces données
→ Une fois ces données liées aux données (observation de l'enseignant, bulletin de note, etc) fournies par l'établissement en fin d'année, les numéros d'étudiants sont supprimés de la totalité des données

Étude ponctuelle:

→ Les établissements partenaires du projet Poppy Éducation et du projet e-Fran PERSEVERNOS (*cf annexe5* - liste établissements partenaires fournissent une population d'élèves pour participer à l'étude.
→ Les données sont anonymes
→ Les enregistrements audio et vidéo sont supprimés après leur retranscription.

Confidentiality Protections

b) Specify the individually identifiable data you will obtain, use or disclose to others.

Étude longitudinale:

→ âge, sexe, classe et établissement d'affectation,
→ bulletin scolaire
→ numéro d'étudiant (supprimés après avoir croisé nos données recueillies avec celles recueillies par l'établissement)

Étude ponctuelle:

→ âge, sexe, niveau d'étude
→ enregistrements audio et vidéo (supprimés après retranscription)

c) Describe: (i) how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop of other portable device); (ii) how you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and (iii) who will have access to the data (e.g., research team, sponsors, consultants)

i. Données collectées et stockées par la plateforme de sondage sécurisée de Inria, puis stockées (pour analyse) sur l'ordinateur du doctorant.
ii. Données en ligne sécurisées par Inria. Données locales codées ("cryptées") par le doctorant sur son ordinateur verrouillé par mot de passe.
iii. Personne d'autre que le doctorant n'aura accès à ces fichiers.

d) ~~If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit~~.

e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.

Un chiffrement par AES-256 (fourni par libreoffice). Seul le doctorant aura accès à la clé de sécurité.

f) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data collected (e.g. conscious of oral and written communications, maintaining paper and electronic data)?

Le personnel de recherche (e g chercheurs, doctorants, ingénieurs et stagiaires) sera informé par le doctorant Thibault Desprez des circonstances de la recherche et ceci par entretien direct ou par groupe de travail. Il leur fournira les différents documents présentant les procédures à suivre (cf annexe4 - homologation de sécurité) pour protéger la vie privée des élèves et enseignants ainsi que la confidentialité des données collectées.

Concernant les enseignants, ils auront la même sensibilisation au respect de la vie privée que les autres membre du personnel de recherche. Dans l'hypothèse où ils auraient à recueillir des données (I.e. grilles d'observations, commentaires écrits sur l'apprenant, etc.) ils seront également formés aux procédures à suivre pour protéger la vie privée des élèves et la confidentialité des données collectées notamment pour l'anonymisation des données.

8. Potential Conflict of Interest

a) Does anyone who:

- *recruits, selects, consents, or treats participants*
- *plans to analyze data*
- *plans to serve as an author on any papers originating from this research*
- *is an immediate family member (spouse, dependent child, domestic partner) of any of the above:*

☐	***Yes***	☒	***No***	*have consulting arrangements, responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?*
☐	***Yes***	☒	***No***	*have a financial relationship with the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s) including the receipt of honoraria, income, or stock/stock options as payment?*
☐	***Yes***	☒	***No***	*serve as a member of an advisory board with the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?*
☐	***Yes***	☒	***No***	*receive any gift funds from the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?*
☐	***Yes***	☒	***No***	*have an ownership or royalty interest in any intellectual property utilized in this protocol?*

b) ☐ ***Yes*** ☒ ***No*** *To your knowledge, does any one in a supervisory role to you have a conflict of interest related to this*

study?

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship, i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor (see sample consent form). The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment (see sample consent form).

***If you answer yes to any of the questions above**, you must file a Conflict of Interest (CoI) disclosure. Contact the IRB secretary at irbphonenumber or irb@inria.fr.*

c) ☐ ***Yes*** ☒ ***No*** *To your knowledge, does INRIA have an ownership or royalty interest in any intellectual property utilized in this protocol?*

9. Consent Background

Written, signed consent should always be sought unless there are compelling reasons to seek an alteration of consent, waiver of consent, or waiver of documentation (i.e., signature). A protocol should include at least one of the following. Depending on the nature of the research and the subject population, more than one may be included.

- Consent
- Waiver of Consent *(e.g., retrospective chart reviews)*
- Waiver of Documentation (Signature) *(e.g., telephone screens, oral consent, web questionnaires, and cases when the primary risk is breach of confidentiality)*
- Alteration of Consent *(e.g., research involving deception or incomplete disclosure)*

Le consentement concerne le recueille des données, la participation aux activités en elle-même est «imposée» aux apprenants par leur enseignant dans le cadre des libertés qu'il possède afin d'établir le parcours pédagogique de sa classe (dans le respect des objectifs -programme officiel- de l'Éducation nationale française).

9.1 Consent

Consent Information Type: Consent
Title: Formulaire de consentement éclairé

Consent to perform privacy monitoring

Sponsor's Consent Version Number:
Consent Form (file name): annexe2 - Formulaire de consentement éclairé

a) Describe the informed consent process. Include the following:

- *Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study).*

  Enfants et tuteur légal

- *When and where will consent be obtained?*

  Durant la première session de passation des études, directement sur le lieu de l'étude

- *How much time will be devoted to consent discussion?*

  Quelques heures

- *Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?*

  Oui

- *What steps are you taking to minimize the possibility of coercion and undue influence?*

  Les établissements partenaires et leurs enseignants sont volontaires dans la réalisation de l'étude ; les élèves n'ont pas le choix de leur enseignement ; les élèves ou leurs tuteurs peuvent refuser l'utilisation des données collectées sur eux-même durant l'étude.

- *If consent relates to children and if you have a reason for obtaining only one parent signature, provide that rationale for IRB consideration.*

  Les études effectuées concernent seulement l'utilisation d'un kit robotique pédagogique dans différents

contextes, aucune altération physique, mentale ou sociale n'est provoquée par cette étude.

b) What is the procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand French or if they have a hearing impairment?

Les établissements partenaires s'engagent à s'assurer de la bonne compréhension du consentement avant la signature de celui-ci.

~~*c) What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.*~~

9.2 Alteration of Consent

La recherche ici menée n'impliquant aucune tromperie ou divulgation incomplète. Ainsi elle ne nécessite pas de «Modification du consentement»

~~*Consent Information Type: Alteration of Consent*~~
~~*Title:*~~
~~*Sponsor's Consent Version Number:*~~
~~*Consent Form (file name):*~~
~~*a) Describe the informed consent process. Include the following:*~~

- ~~*Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study).*~~
- ~~*When and where will consent be obtained?*~~
- ~~*How much time will be devoted to consent discussion?*~~
- ~~*Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?*~~
- ~~*What steps are you taking to minimize the possibility of coercion and undue influence?*~~

~~*If consent relates to children and if you have a reason for obtaining only one parent signature, provide that rationale for IRB consideration.*~~

~~*b) What is the procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand French or if they have a hearing impairment?*~~

~~*c) What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.*~~

~~*Address the following four regulatory criteria for an alteration of consent and provide protocol- specific justification for each:*~~

~~☐ **True** ☐ **False** **The research involves no more than minimal risk to the participants.**~~

~~*Example: The research involves a review of medical records to determine the incidence of infection following hip replacement procedures. Participant information will be coded, and the key linking identities to the code will be kept in a locked cabinet to which only the Protocol Director and one co-investigator have access.*~~

~~*Rationale for above selection:*~~
~~_____~~

~~☐ **True** ☐ **False** **The waiver or alteration will not adversely affect the rights and welfare of the participants.**~~

~~*Example: The Privacy Notice informs patients that their records may be used without their authorization if approved by the IRB, and because study procedures are in place to protect confidentially (including coding and restricted access to the key) information learned during the study will not affect the treatment of the participants who had infections in the pasts and thus will not adversely affect their welfare.*~~

~~*Rationale for above selection:*~~
~~_____~~

~~☐ **True** ☐ **False** **The research could not practically be carried out with out the waiver or alteration.**~~

~~*Example: If the IRB required informed consent of participants, this research would be impracticable to do because it would require contacting 1000 patients who had hip replacements one to four years ago; many are elderly and may have moved following their procedure, such that accurate contact information is not readily available and obtaining it for any of the target population would be unduly burdensome.*~~

~~*Rationale for above selection:*~~
~~_____~~

~~☐ True ☐ False Whenever appropriate, the participants will be provided with additional pertinent information after participation.~~

~~*Example: The information expected to be learned from this retrospective chart review from patient cases one to four years ago will not affect participant's treatment in the future. Thus, it is not anticipated that there will be pertinent information for study participants, though the study may lead to articles about infection that may affect the treatment of future patients.*~~

~~*Rationale for above selection:*~~

9.3 Waiver of Consent

Consent Information Type: Waiver of Consent
Title:

Waiver of content for the large-set of users

Address the following four regulatory criteria for a waiver of consent and provide protocol-specific justification for each:

☒ **True** ☐ **False** **The research involves no more than minimal risk to the participants.**

Example: The research involves a review of medical records to determine the incidence of infection following hip replacement procedures. Participant information will be coded, and the key linking identities to the code will be kept in a locked cabinet to which only the Protocol Director and one co-investigator have access.

Rationale for above selection:

☒ ***True*** ☐ ***False*** ***The waiver or alteration will not adversely affect the rights and welfare of the participants.***

Example: The Privacy Notice informs patients that their records may be used without their authorization if approved by the IRB, and because study procedures are in place to protect confidentially (including coding and restricted access to the key) information learned during the study will not affect the treatment of the participants who had infections in the pasts and thus will not adversely affect their welfare.

Rationale for above selection:

☐ ***True*** ☒ ***False*** ***The research could not practically be carried out with out the waiver or alteration.***

Example: If the IRB required informed consent of participants, this research would be impracticable to do because it would require contacting 1000 patients who had hip replacements one to four years ago; many are elderly and may have moved following their procedure, such that accurate contact information is not readily available and obtaining it for any of the target population would be unduly burdensome.

Rationale for above selection:

☒ ***True*** ☐ ***False*** ***Whenever appropriate, the participants will be provided with additional pertinent information after participation.***

Example: The information expected to be learnt from this retrospective chart review from patient cases one to four years ago will not affect participant's treatment in the future. Thus, it is not anticipated that there will be pertinent information for study participants, though the study may lead to articles about infection that may affect the treatment of future patients.

9.4 Waiver of Documentation

Il est envisagé de passer par les systèmes numériques des lycées (type «Pro Note») pour fournir les informations préliminaires sur les activités suivies en classe par les élèves et sur le caractère expérimental de celles-ci. Pour des économies d'impression, les enseignants souhaiteraient pouvoir également transmettre les informations relatives aux recueille des données et le consentement éclairé (en PDF) via ce même système pour, dans un second temps, répondre aux éventuelles questions et récupérer les accords (c-à-d la signature) via le «carnet de liaison»Il n'y a donc pas réellement de renonciation à la documentation.

Consent Information Type: *Waiver of Documentation*
Title: Email consent
Sponsor's Consent Version Number:

a) *D*escribe the informed consent process. Include the following:

- Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study).

Les enseignants référents de chaque lycée

- When and where will consent be obtained?

Au lancement des expérimentations, sur les systèmes numériques des lycées ou sur le «carnet de liaison» de l'apprenant.

- How much time will be devoted to consent discussion?

Tant qu'il y aura des interrogations de la part des participants ou de leurs tuteurs légaux

- Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?

La participation aux activités étant réalisé dans le cadre des activités normales d'éducation, les participants ont jusqu'à la fin des expérimentations pour se prononcer sur l'utilisation ou non des données issues de ces activités.

- What steps are you taking to minimize the possibility of coercion and undue influence?

Aucune

- If consent relates to children and if you have a reason for obtaining only one parent signature, provide that rationale for IRB consideration.

Les données recueillies ayant un degré de sensibilité plutôt faible (*cf* annexe4 CNIL) et afin de ne pas augmenter la charge de travail des enseignants volontaires, il serait préférable qu'une seule signature soit recueillie.

b) What is the procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand French or if they have a hearing impairment?

Les enseignants s'assureront, par questionnement oral, de la bonne compréhension des informations contenues dans le consentement éclairé, notamment dans le cas de personnes n'ayant pas une bonne pratique de la langue française. Les divers documents pourront, suivant les cas, faire l'objet d'une traduction.

c) What steps are you taking to determine that potential subjects are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

Les enseignants s'assureront, par questionnement oral, de la capacité des sujets à participer aux expérimentations

Select one of the following regulatory criteria for a waiver of documentation (signature) and provide a protocol-specific justification:

☒ For research that is not subject to regulation, the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.

☐ Research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

10. Assent Background (Less than 18 years of age)

All children must assent to participating by signing an assent form, unless the investigator(s) provides evidence to the IRB that the children are not capable of assenting because of age, maturity, psychological state, or other factors. A protocol that involves children should include at least one of the following. Depending on the nature of the research and the subject population, more than one may be included.

- *Assent*
- *Waiver of Assent (used when assent will not be sought for some or all of the children* ***capable*** *of assenting)*
- *Assent Not Applicable (used to describe why some or all of children are not capable of assenting)*

Le consentement concerne le recueille des données, la participation aux activités en elle-même est «imposée» aux apprenants par leur enseignant dans le cadre des libertés qu'il possède afin d'établir le parcours pédagogique de sa classe

(dans le respect des objectifs -programme officiel- de l'Éducation nationale française).
Cependant les participants mineurs auront accès aux même informations que l'ensemble des participants.

10.1 Assent

Assent Information Type: *Assent*
Title:
Sponsor's Assent Version Number:
Assent Form (file name):

a) *D*escribe the assent process. Include the following:

- Who is obtaining child assent? (The person must be knowledgeable about the study.)

  Les enseignants référents de chaque lycée.

- When and where will assent be obtained?

  Au lancement des expérimentations, en classe

- Will a parent or guardian be present when assent is obtained?

  Non, mais le consentement de l'élève sera recueillie (oralement) avant la signature du consentement éclairé par son tuteur légal qui s'assurera de sa bonne compréhension.

- How much time will be devoted to the assent discussion?

  Tant qu'il y aura des interrogations de la part des participants.

- Will these periods provide sufficient opportunity for the child to consider whether to assent?

  L'enfant peut à différentes reprises reconsidérer son consentement: à la présentation des activités par l'enseignant en classe ; à la présentation des activités et du consentement éclairé par l'enseignant aux tuteurs légaux ; au lancement des activités ; durant les activités.

- What steps are you taking to minimize the possibility of coercion and undue influence?

  L'enfant possède deux références (son enseignant et son tuteur) pour contrebalancer les effets d'influence qui peuvent s'exercer sur lui.

b) What is the procedure to assess the child's understanding of the information contained in the assent? How will the information be provided to the child if he/she does not understand English or has a hearing impairment? How will affirmative assent be obtained, e.g., documented by signature on assent form, oral response, combination of methods, or other?

Les enseignants s'assureront, par questionnement oral, de la bonne compréhension des informations contenues dans le consentement éclairé, notamment dans le cas de personnes n'ayant pas une bonne pratique de la langue française. Les divers documents pourront, suivant les cas, faire l'objet d'une traduction.

c) What steps are you taking to determine that the child has the capacity to participate in the decision-making process? Will consent be obtained from both parents (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child), or from just one parent? Provide a rationale if only one parent will consent.

Les enseignants s'assureront, par questionnement oral, de la capacité des sujets à participer aux expérimentations

10.2 Waiver of Assent

Consent Information Type: *Waiver of Assent*
Title:
Address the following four regulatory criteria for a waiver of consent and provide protocol-specific justification for each:

☒ **True** ☐ **False** **The research involves no more than minimal risk to the participants.**

Rationale for above selection:

☒ **True** ☐ **False** **The waiver or alteration will not adversely affect the rights and welfare of the participants.**

Rationale for above selection:

☐ **True**	☒ **False**	**The research could not practically be carried out with out the waiver or alteration.**
		Rationale for above selection:
☒ **True**	☐ **False**	**Whenever appropriate, the participants will be provided with additional pertinent information after participation.**

Rationale for above selection:

10.3 Assent Not Applicable

Consent Information Type: Waiver of Assent
Title:
Please explain why assent is not applicable to this study.

11. Other Legal aspects

Does your research might impact a specific infrastructure, company or violate terms of a provider's terms of use for their service and the provider's intellectual property rights, such as unauthorized use of trademarks and violation of copyrights? Please explain why you cannot avoid this and the actions to mitigate this.

12. Attachments

12.1 Advertisements

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

12.2 Cooperating Institution(s) Approval

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

12.3 Federal Grant/Sub-contract

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

12.4 Information Sheets/Brochures

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

12.5 Package Inserts

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

12.6 Phone Scripts

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

12.7 Program Project Grant/List

Attachment Name:
Attached Date:
Attached By:
Submitted Date:

12.8 Questionnaires
Attachment Name:
Attached Date:
Attached By:
Submitted Date:
12.9 Sponsor's Protocol
Attachment Name:
Attached Date:
Attached By:
Submitted Date:
12.10 Sponsor's Protocol Amendments
Attachment Name:
Attached Date:
Attached By:
Submitted Date:
12.11 Training Grant/List
Attachment Name:
Attached Date:
Attached By:
Submitted Date:
12.12 Un-sponsored Research Approval
Attachment Name:
Attached Date:
Attached By:
Submitted Date:
12.13 Other
Attachment Name:
Attached Date:
Attached By:
Submitted Date:

Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research
- protection ethical principles, regulations, policies and procedures
- Ensure all research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Disclose to the appropriate departments any potential conflict of interest
- Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
- Apply relevant professional standards.

Any change in the research protocol must be submitted to the IRB for review prior to the implementation of such change. Any complications in subjects or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project. Inasmuch as the Institutional Review Board (IRB) include faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

IRB approval of any project is for a maximum period of one year. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.

Inria's Research Center director must approve the protocol application.

All data including signed consent form documents must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency or other entities.

List all items (verbatim) you want to be reflected in your approval letter, i.e. Amendment, Investigator's Brochure, consent form(s), advertisement, telephone script, diary card, etc. Include number and date when appropriate.

☐ The Protocol Director has read and agrees to abide by the above obligations.